DOCUMENT RESUME

ED 213 288 HE 014 635

TITLE	Report of the AACP Conference on Guidelines for Doctor of Pharmacy Programs (Kansas City, Missouri, October 26-28, 1975).
INSTITUTION	American Association of Colleges of Pharmacy, Bethesda, Md.
PUB DATE	76
NOTE	119p.
AVAILABLE FROM	American Association of Colleges of Pharmacy, 4630 Montgomery Avenue, Suite 201, Bethesda, MD 20014 ($4.00 members, $5.00 nonmembers).
EDRS PRICE	MF01 Plus Postage. PC Not Available from EDRS.
DESCRIPTORS	*Academic Standards; Accreditation (Institutions); *Behavioral Objectives; *Clinical Experience; College Curriculum; College Faculty; *Doctoral Programs; Evaluation Criteria; Guidelines; Higher Education; Internship Programs; *Pharmaceutical Education; Pharmacy; Professional Education; Student Evaluation
IDENTIFIERS	*American Council on Pharmaceutical Education

ABSTRACT

Recommendations regarding Doctor of Pharmacy programs are presented, based on reactions to American Council on Pharmaceutical Education tentative guidelines to its published "Standards." The reactions to the guidelines were expressed at an open hearing held at the 1975 Annual Meeting of the American Association of Colleges of Pharmacy. Recommendations that were developed at the conference workshops concern: competencies expected of the Doctor of Pharmacy program graduate, the curriculum, evaluation of student performance, criteria for admitting students, types of faculty, qualifications of faculty, and service roles. Curriculum areas are as follows: basic science and preclinical components, structure of the clinical component, the introductory clinical clerkship, required clinical clerkships, selective-elective clinical clerkships, and time distribution in clinical clerkships. Miscellaneous curriculum considerations include: outpatient and ambulatory care experiences; student responsibilities and the degree of supervision in the clinical component of the curriculum; the relationship of the clinical component to postdoctoral residencies; and social, behavioral, and anthropological aspects of Doctor of Pharmacy education. In addition to specific recommendations, issues that are important to the charge and recommendations are identified, along with points of difference or controversy among the workshops. A synopsis of discussions and important remarks that were made by conference participants during the general session, position papers on workshop topics, charges to workshops and instructions for workshop participants are included. (SW)

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REPORT OF THE AACP CONFERENCE ON GUIDELINES FOR DOCTOR OF PHARMACY PROGRAMS

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Conference Steering Committee

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Donald L. Sorby, Ph.D., Chairman.

October 26-28, 1975
Kansas City, Missouri

Purpose of Report

This report has been prepared with the intent that it can be recommended to the American Council on Pharmaceutical Education for use to supplement and better define the previously published Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy. The recommendations contained in this report are not presented with the intent to replace the "Tentative Guidelines." This document should also be useful to pharmacy educators planning to implement a doctor of pharmacy curriculum. To persons outside pharmaceutical education, this report should serve to further clarify the format and purpose of the doctor of pharmacy curriculum.

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Preface

Background

In January, 1975, the American Council on Pharmaceutical Education published the seventh edition of the Accreditation Manual, which for the first time contained standards for accrediting academic programs leading to award of the doctor of pharmacy degree. Approximately six months later, the Council published a document titled, "Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy." The Council announced its intent to evaluate all currently operational doctor of pharmacy degree granting programs by the end of 1976. An open hearing was held by Council representatives at the Annual Meeting of the American Association of Colleges of Pharmacy in July, 1975, for purposes of obtaining from Association members their reaction and input to the "Tentative Guidelines." During this hearing, many persons expressed opinion that the "Guidelines" should be made more specific with respect to such matters as program objectives, curriculum content, qualifications of faculty, required facilities and procedures for evaluating students. Furthermore, concern was expressed that all currently existing programs offering the doctor of pharmacy degree might not be subjected to a uniform set of criteria during the forthcoming round of accreditation reviews since the guidelines were obviously still in an evolutionary stage. Subsequent to this hearing, the following resolution was adopted by the AACP House of Delegates:

> "Whereas, the American Council on Pharmaceutical Education has previously established Standards for accreditation of Pharm.D. programs and has more recently published 'Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy,' a manuscript containing tentative guidelines to the published Standards, and,
>
> Whereas, these 'Tentative Guidelines' fail to insure the quality of an accredited Pharm.D. program, and,
>
> Whereas, there exists among those institutions currently offering the Pharm.D. degree a considerable consensus on a number of specific criteria characterizing quality doctoral level education and training which could be utilized by the Council for improving the 'Tentative Guidelines,' and,
>
> Whereas, experience gained by the Council during the first round of accreditation visits of currently operational Pharm.D. programs should also lead to an improved set of guidelines by approximately January, 1977, therefore,
>
> Be it resolved, that AACP convene a special conference or workshop of all member institutions prior to January 1, 1976, for the purpose of obtaining a broad input of expertise from faculty experienced in Pharm.D. level education and training, to be transmitted to the Council in the form of specific recommendations for the development of 'Guidelines' for Pharm.D. program evaluation, and,

Be it Further Resolved, that this Association appeal to the American Council on Pharmaceutical Education to defer final decision on accreditation of any and all Pharm.D. programs until the initial round of accreditation visits of currently operational programs is completed and the 'Guidelines' for Pharm.D. program evaluation are developed, with the understanding that this will be done by approximately spring of 1977.

In response to this resolution, the Board of Directors of AACP assigned the responsibility of organizing and conducting the conference to Donald L. Sorby, Dean, School of Pharmacy, University of Missouri-Kansas City. The Board of Directors authorized formation of a steering committee of not more than four persons in addition to Dr. Sorby, who was to serve as Chairman. All pharmacy schools and colleges were to be invited, but attendance was to be limited to two delegates per school. The Steering Committee subsequently interpreted this limitation to not apply to persons who were members of the Steering Committee or who prepared discussion papers in support of the Conference program.

The Conference Steering Committee was constituted, with the following persons as members:

William Barr, Pharm.D., Ph.D.
Professor of Pharmacy
Virginia Commonwealth University

Mary Anne Kimble, Pharm.D.
Assistant Clinical Professor of Clinical Pharmacy
Vice Chairwoman, Division of Clinical Pharmacy
University of California, San Francisco

William Miller, Pharm.D.
Associate Professor of Clinical Pharmacy
Director, Division of Clinical Pharmacy
University of Tennessee

Charles C. Pulliam, M.S.
Assistant Professor of Clinical Pharmacy
University of North Carolina

Donald L. Sorby, Ph.D.
Dean, and Professor of Pharmacy
University of Missouri-Kansas City

The Conference was held October 26, 27, and 28, 1975, in Kansas City, Missouri. Sixty-five schools were represented at the Conference. A list of participants appears in Appendix I.

Procedure

The Steering Committee identified six key elements of the Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy which

they felt should be considered in detail by the conference participants. It was decided that the conference would be conducted according to a workshop format. Every effort would be made to identify those points where a consensus could be reached regarding recommendations for inclusion in the "Tentative Guidelines."

The Steering Committee retained the services of Helgola G. Ross, Ph.D., Assistant Professor of Education at the University of Cincinnati, to assist with the design of workshop procedures. Dr. Ross's specific assignment was to recommend procedures and to conduct suitable training sessions for conference participants so as to increase productivity of the workshops and maximize consensus development. The following general procedure was used for workshops.

Each conference participant was assigned to be a member of a "basic" workshop group. These groups numbered six to eight persons. Each basic workshop was given one assigned charge around which to develop recommendations. These charges related to the six key elements identified by the Steering Committee. Twelve different charges were addressed by workshop groups. With exception of two of the charges, each was considered simultaneously by two different workshop groups. A list of the charges appears in Appendix II. The workshop assignments were made in advance of the conference. Each registrant was asked to prepare recommendations, in advance of the Conference, to answer the workshop charge. Prior to the Conference, the Steering Committee requested several persons to prepare papers relative to the "six key elements" which could serve as discussion stimulators. Two, or in some cases three, papers were prepared for each key element. Persons invited to prepare these papers were known by the Committee to be especially qualified for the specific task. The papers were distributed to all participants 10 days in advance of the date of the Conference. Because these papers contain much valuable information not included in the Conference report, they are included as Appendix III. It is emphasized that material contained in these papers is based upon personal opinions of the authors and does not necessarily represent the consensus of Conference participants.

The Conference itself began with an evening training session conducted by Dr. Ross. The workshop groups learned to work together toward reaching consensus and resolving differences. This training exercise was done to maximize the probability of the group reaching productive conclusions in carrying out their charge. Appendix IV contains Dr. Ross's directions to workshop participants. Four workshop sessions were then held on the second day of the Conference. In the first two-hour session, each basic workshop group discussed their assignment and "brainstormed" possible recommendations without arguing their relative merits or attempting to develop consensus. This session was followed by two one-hour "secondary" workshop sessions. During these sessions, each Conference attendee was provided opportunity to meet with a representative of two different basic workshop groups. The recommendations of the basic group were reviewed, suggestions for additions were made, as were comments about specific items. These were recorded by a member of the basic group, who had been designated to receive the input during these secondary sessions. During a final two-hour session, the basic workshop groups reconvened. During this session they reviewed their list of potential recommendations, as well as the

suggestions obtained from the secondary sessions. Overlap and duplication were first eliminated, and then the group tried to identify all recommendations where there was agreement. Where disagreement existed, this was discussed. In some cases, this discussion reloved differences. If differences could not be resolved, they were so identified in the workshop report. At the conclusion of the session, one member of the group was designated to prepare a summary report containing the recommendations.

Day Three of the Conference was devoted to presentations of workshop reports to a general session of all Conference attendees. All reports were available in written form at the time of presentation. Discussion periods of 15 to 25 minutes followed each report. Important remarks and comments from the audience were recorded by the program chairman and members of the Steering Committee.

Following the Conference, the Chairman prepared a draft report containing the workshop recommendations, along with summaries of important comments from the discussion session. This draft was reviewed by members of the Steering Committee and by one member of each Basic Workshop Group. Suggestions resulting from this review were incorporated into the final copy of the report. The report was submitted in December, 1975, to the Board of Directors of the American Association of Colleges of Pharmacy, with recommendation that it be transmitted to the American Council on Pharmaceutical Education for possible incorporation into their Guidelines for Doctor of Pharmacy Degree Programs.

Report Format

This report has been prepared to represent a synthesis of the recommendations from the workshops and important comments made during the general discission session. The report is organized to represent a flow of thought beginning with statements of expected competencies, extending through curriculum matters, and ending with considerations of faculty and facilities. Because there was considerable overlap between workshop recommendations, the individual workshop reports have not been reprinted as such. However, all workshop recommendations are contained in this report. Each major component of the report identifies the charges given to workshops which relate to the component topic. Following each charge is a section titled Recommendations. These are the recommendations on which there was a consensus by workshop groups. In some cases, the recommendations are followed by a section titled Remarks. This section identifies issues important to the charge and recommendations. In this section, points of difference or controversy among the workshops are identified. Most components also contain a section headed Comments from the General Session. These represent a synopsis of discussions and important remarks which were made by Conference participants during the general session on the second day of the Conference. It must be pointed out that these represent opinions and recommendations of individuals or groups of individuals, and are not necessarily the consensus of the Conference attendees. Some of these relate to recommendations of the workshop groups, others are supplemental. In general, there appeared to be a high degree of consensus among Conference participants regarding the workshop recommendations.

It is important to note before reading this report that the primary focus of the Conference and its workshops was on identifying those curricular elements and expectations which make the Doctor of Pharmacy degree program unique. Throughout the report, assumptions are made that the baccalaureate curriculum provides a certain base of education and experience which will be common to the doctor of pharmacy program. The recommendations contained in this report should generally be taken in the context that a certain base provided by bacccalaureate programs will exist in the graduates' educational background. Those doctor of pharmacy programs which are designed as the "first professional degree" would be expected to also provide this base. The reader's attention is also directed to the section titled Recommendations of the Steering Committee for further remarks concerning this matter.

COMPETENCIES EXPECTED OF THE DOCTOR OF PHARMACY GRADUATE

COMPETENCY EXPECTATIONS

Charge: Develop a series of statements which describe--in a general way--those broad competencies which a Pharm.D. program graduate should possess, regardless of program emphasis. These should lead toward helping distinguish doctoral from baccalaureate level programs.

Editorial Notes: The Steering Committee considered at length the degree or depth to which the conference should develop statements of competency expected of the Doctor of Pharmacy program graduate. It is recognized that many programs are only in the initial stages of developing detailed lists of competency expectations. Furthermore, competency expectations will vary among different institutions, depending on program objectives. Most programs are in an evolutionary process and this causes detailed competency lists to be in a continual state of change. Finally, methods to evaluate achievement of competencies are generally not sufficiently well developed at this time that use of competency statements as indicators of program success could be generally applied in the accreditation process. It was, therefore, decided by the Committee that the Conference should only attempt to identify those broad competency areas and student performances which should be fundamental to any doctor of pharmacy program, and which might distinguish it from baccalaureate education.

Several workshop groups developed lists of competencies which the graduate of the Doctor of Pharmacy degree program should possess. Although these lists were similar in some respects, there were significant differences. This section reports two of these lists. One was developed by the workshop groups specifically assigned this task. A second list was developed by one of the workshop groups assigned the task of making recommendations concerning procedures for evaluating students. In addition, the following section presents the report of workshop groups assigned the task of defining the hallmarks of the "professionally more mature graduate". This is also phrased in terms of competency expectations. All of these are reported for the sake of completeness.

Recommendations for this section are derived from the reports of workshop groups 3-A/B, 5-C/D, and 6-B.

Recommendations

The graduate of a Doctor of Pharmacy program should demonstrate competency in performing the following activities:

1. From a verbal or written patient presentation (signs, symptoms, lab tests, diagnoses) recognize and list important medical problems, disease states, symptoms, or abnormal laboratory values which may:

   a. Require, or indicate need for, drug therapy

b. Be aggravated or induced by drug therapy

c. Eventually alter the selection and/or dosing regimen of drugs; e.g., renal function, liver function, allergies, bowel resection.

2. Establish and expand the patient data base; e.g., through drug history, medical history, physical exam, progress notes.

3. Design a therapeutic regimen or plan, based on patient-specific information. This would include:

   a. Establishing a therapeutic endpoint
   b. Selecting appropriate drug and related therapy
   c. Establishing an appropriate dosage regimen

4. Independently monitor and assess therapeutic and adverse effects of drug therapy through selection and evaluation of physical and laboratory parameters.

5. Supervise patient management for specified chronic diseases.

6. Utilize knowledge of pharmacokinetics and other patient parameters to design dosage regimens.

7. Critically evaluate drug literature. (This assumes the Pharm.D. graduate understands the proper method of research design and evaluation.)

8. Effectively communicate (verbally or in writing) with patients, peers, and other health professionals about all aspects of drug therapy.

Comments from General Session

The ability to act independently in performing these functions is a cardinal feature of the doctor of pharmacy. This ability distinguishes him/her from the baccalaureate program graduate, who may possess some of these competencies, but not to the extent of being capable of performing them without close supervision.

Item 5 may be challenged with respect to its uniqueness to the Doctor of Pharmacy. Supervision of patients with chronic diseases may be within the capabilities of some baccalaureate program graduates. This function might also be--and is--performed by nurse practitioners and some physician extenders.

Additional Statements of Competency Expectations: The workshop group studying Evaluation and Student Qualifications identified four categories of terminal behavior expected of the Doctor of Pharmacy graduate.

The graduate of a Doctor of Pharmacy program must demonstrate ability to:

1. Promote rational drug therapy.

2. Integrate the psycho-socio-economic aspects of patient care into professional practice.

3. Be responsive to the changes in health care delivery policies and systems.

4. Identify problems and conduct clinical research.

THE PROFESSIONALLY MORE MATURE GRADUATE

Charge: On Page 8, the "Tentative Guidelines" state that "ample opportunity for professional decision making and the acquisition of clinical judgment skills should be provided so as to insure compliance with the standard that the 'program will develop students professionally more mature than those in the baccalaureate programs'".

What are the hallmarks of the professionally more mature graduate?

Recommendations

The following abilities are considered to be the hallmarks of the professionally more mature graduate. The graduate of the Doctor of Pharmacy program should be able to:

1. Independently identify and assess patient parameters relative to monitoring the effectiveness and adversities of drug therapy, utilizing:

   a. A Medical history
   b. Appropriate physical findings
   c. Laboratory tests
   d. Diagnostic tests
   e. Serum concentrations of drugs

2. Utilize a comprehensive data base, in combination with knowledge about inculcating pathophysiology, therapeutic principles, pharmacokinetics and toxicology, to provide consultation necessary to the patient care decision-making process.

3. Define acceptable therapeutic goal(s) and end point (s).

4. Select and implement the therapeutic agent(s) most appropriate to individual patient variables.

5. Efficiently and effectively utilize drug information retrieval systems to provide consultation and influence the patient care decision-making processes.

6. Demonstrate a sense of personal and professional responsibliity for their patient's medical management.

7. Perform independent research.*

8. Communicate effectively and work harmoniously in the provision of quality health care.

In addition, the professionally more mature graduate should also possess confidence commensurate with his/her level of competence.

*See editorial note on page 8.

THE CURRICULUM

THE BASIC SCIENCE AND PRE-CLINICAL COMPONENT OF THE CURRICULUM

[Recommendations for this section derived from reports of Workshop Groups 4-A and 4-B.]

Charge: On page 6, the "Tentative Guidelines" state, "Standards require demonstration of 'a professionally oriented curriculum with biomedical and clinical experience significantly beyond that provided in the baccalaureate program'".

This workshop should develop a description of the basic curriculum format which is required to establish the basic science and pre-clinical component of the Pharm.D. program.

Types of courses (by discipline), approximate time devoted to each, and levels of sophistication to be achieved should be stated. Qualitative and quantitative differences form baccalaureate-level courses should be identified where possible.

Which basic science courses are a "must" and which are "desirable"?

Assumptions and Conditions: It was assumed that the Pharm.D. curriculum would include most of the subjects fundamental to baccalaureate programs. The Workshop Groups then considered the need for expansion on this base. The basic science and pre-clinical curriculum was approached by topic area rather than by course. Course names and designation will vary among the colleges offering Doctor of Pharmacy programs. It was assumed that the clinical applications of biopharmaceutics, pharmacokinetics and therapeutics would be part of the clinical curriculum.

Recommendations

Subject matter in the basic sciences and pre-clinical curriculum is divided into three categories. These categories include, but are not necessarily restricted to, the following subjects.

Category A--Subject matter in pharmaceutical and biomedical sciences, which is typically included in baccalaureate programs and which may, but not necessarily, require reinforcement but not expansion in Pharm.D. programs.

1. Biological Sciences: General biology, microbiology, pathology, general pharmacology, anatomy, biochemistry, physiology.

2. Physical Sciences and Mathematics: General chemistry, organic chemistry, analytical chemistry, calculus.

3. Pharmaceutical Sciences: Pharmaceutics, medicinal chemistry-pharmacognosy.

4. Pharmacy Administration and Practice: Dispensing, jurisprudence,

economics, management, accounting.

5. Other: Public health.

This category also assumes an appropriate treatment of subject matter, which is often obtained in community colleges and colleges of liberal arts, as cited on page 14 of the Accreditation Manual.

Category B--Subject matter in pharmaceutical and biomedical sciences which is generally included in baccalaureate programs, but which requires reinforcement and expansion in Pharm.D. programs.

1. Biomedical Sciences: Biochemistry, medical microbiology, human physiology, pathophysiology, immunology, therapeutics, clinical pharmacology and toxicology.

2. Pharmacy Administration and/or Community Medicine: Health care administration, social policies in health care, professional services management.

3. Pharmaceutics: Biopharmaceutics and pharmacokinetics.

Supplemental note: Comprehension of the biochemical, immunological, microbiological, pathological, and physiological aspects of disease processes is a prerequisite to the comprehension of drug pharmacodynamics and therapeutics. The terminal behavior expected of students completing the Biomedical Sciences sequence is to be able to utilize this information to provide drug information to patients and health care practitioners, monitor drug therapy, aid in diagnosing drug-related or drug-induced disorders, and assist in developing individualized therapeutic regimens.

The courses cited under Pharmacy Administration and/or Community Medicine should cover the organization, provision, and financing of health care services, with emphasis on pharmacy. In addition, the legislative, political, and socioeconomic factors affecting health care practices, procedures, and policies should also be treated.

Biopharmaceutics and pharmacokinetics should include the application of basic principles to the actual use of drugs in therapy. The terminal behavior expected of students is to provide drug information and consultation on the biopharmaceutic and pharmacokinetic factors influencing the choice and effectiveness of drug therapy and to participate in developing and modifying drug dosage regimens.

Category C--Subject matter in pharmaceutical and biomedical sciences generally not included in baccalaureate programs, both which is required or desirable in Pharm.D. programs.

1. Biomedical Sciences: Clinical pathology.

2. Behavioral Sciences: Psycho-social determinants of disease, organizational behavior, communications.

3. Biostatistics and Research Design

4. Directed Research

Supplemental note: A course in clinical pathology should cover the objectives, techniques, and significance of clinical laboratory tests, and procedures used in the diagnosis and treatment of disease. Some programs may prefer to incorporate these concepts within the therapeutics and clerkship sequences. The terminal behavior expected of students is to utilize the principles of clinical laboratory medicine in monitoring drug therapy and to provide information on drug-laboratory test interactions.

Coverage of the psycho-social determinants of disease should include the psychological factors and sociological patterns influencing the epidemiology of the response to disease.

Courses in biostatistics and research design should: a) familiarize students with the basic concepts and methods used in statistical analyses and inference procedures, b) assist students in evaluating clinical research reported in the literature, and c) provide students with insight into the basic planning considerations required for developing, implementing, and evaluating studies. The terminal behavior expected of students is to apply statistical principles in evaluating clinical research and to participate with confidence in research projects.

Pharm.D. students should undertake an independent research project, supervised by a research committee, in order to develop skills useful in problem identification, research design, data collection, evaluation, and resolution. The terminal behavior expected of students is to apply the scientific method in problem solving and research participation.

Remarks

The workshop groups failed to reach a unanimous opinion only with respect to the directed research recommendation. Some workshop members supported the concept that the Doctor of Pharmacy student should undertake an independent research project, supervised by a research committee, in order to develop skills useful in problem identification, research design, data collection and evaluation and resolution of the problem. Other workshop members felt that the directed research project should be a desirable, but not required, activity. These persons felt that the student should possess the ability to organize and analyze information in a scientific manner. However, they did not feel that a directed research project was the only method to obtain and demonstrate this ability.

Comments from General Session

One Conference participant pointed out that clinical faculty at many institutions may be required to conduct independent research in order to qualify for promotion. However, the ability to do this requires considerable time to develop.

It was suggested that there is insufficient time to develop such an ability within the limitations of the Doctor of Pharmacy curriculum. A contrast was made to the significantly longer period of time required to prepare a Doctor of Philosophy candidate to do research. The question was posed concerning whether the Doctor of Pharmacy candidate needs to actually do research in order to understand methodology and the scientific process. Some discussion concerned the differences between the short research project envisioned for the Doctor of Pharmacy candidate and the original research required for the Doctor of Philosophy degree. It should also be noted that the report of Workshop Groups considering the role of post-doctoral residencies recommended that the conduct of clinical research be a component of such programs.

Editorial Note: Readers of this report will find that directed research projects are included in the recommendations relative to several discussion items. During the General Session of the Conference, there usually occurred considerable discussion about the advisability of a directed research requirement each time it was recommended in a Workshop report. The above comments represent a synopsis of these discussions. The nature of the directed research project and the amount of time which should be devoted to it as a requirement for the Doctor of Pharmacy degree were not resolved by this Conference.

It was noted that the Doctor of Pharmacy must eventually move out of the medical center into other practice settings. This may include being an independent practitioner. This will require an ability to manage the practice in a cost effective manner. Health economics, management and drug marketing should thus be part of the Doctor of Pharmacy program. This position was strongly challenged. Many Conference participants considered such background to be adequately covered by the predoctoral curriculum and that these subjects should not require special emphasis in the Doctor of Pharmacy program.

It was noted that the focus of the Conference was on doctoral education in the context of what additional competencies, courses and activities should be included beyond the baccalaureate degree level. However, it must be kept in mind that there are wide variations in content and quality of baccalaureate programs. The assumption that a common base is provided by the baccalaureate curriculum to all students is probably incorrect.

Computer technology should be added to Category B or Category C. This should include consideration of both digital and analog computation.

THE CLINICAL COMPONENT OF THE CURRICULUM

(Recommendations for this section are derived from reports of Workshop Groups 5-A/B, 5-C/D, 5-E, and 7.)

Charge: The "Tentative Guidelines" recommend 1500 hours as the minimum clinical experience. What are the fundamental types of clinical experiences which are required for quality doctoral education and which should comprise a part of the 1500 hour requirement? What should be the relative amounts of time devoted to the various types of required experiences? Recommendations should be developed for the approximate amount and types of elective experiences which should be made available. What should be the amount and nature of interdisciplinary involvement in these clinical experiences?

Recommendations

Structure of the Clinical Component: The general pattern of the clinical component would include an introductory clinical clerkship which is integrated with and conducted simultaneously with the basic didactic coursework. This would be followed by a full-time clinical clerkship during which there is no major didactic coursework. The full-time clinical clerkship includes required and elective components.

The Introductory Clinical Clerkship

Goals: The student should participate in patient care with a degree of responsibility commensurate with the level of his/her data base and skills. The following specific skills should be developed by the student during this introductory clinical clerkship:

1. Ability to integrate didactic concepts with clinical experience.
2. Ability to observe and analyze the signs and symptoms of disease.
3. Ability to obtain a patient data base suitable for identifying and solving problems.
4. Ability to counsel patients about the appropriate use of medications.
5. Ability to organize and present an assessment of the patient's problems.

Requirements:

1. There should be contact with a role model practitioner.
2. This clerkship should take place in an inpatient facility which may be any appropriate medical service area.
3. The introductory clerkship should comprise a minimum of 200 hours with blocks of time equal to not less than 4 hours available each day.
4. Not more than four students should be assigned per faculty member.
5. The following student experiences should be provided:
   a. Patient interviewing and communication.
   b. Monitoring individual patient drug therapy programs.
   c. Case presentations and medical and pharmacy conference.
   d. Patient education.
   e. Medical record keeping (P.O.M.R. desirable).
   f. Drug information retrieval and evaluation.
   g. Rounds with other health care professionals.
   h. Basic patient assessment.

The Required Clinical Clerkship

Goals: The following specific skills should be developed during this clerkship.

1. Ability to utilize a comprehensive data base in the following areas: pathophysiology, therapeutics, pharmacokinetics and toxicology.

2. Ability to identify and assess patient problems.

3. Ability to define the therapeutic goal(s) and endpoint(s).

4. Ability to select the most appropriate therapeutic agent(s) and regimen(s) depending on patient and drug variables.

5. Ability to monitor the effects of drug therapy based upon selected indices of effect.

6. Ability to implement appropriate changes in drug therapy based upon patient response.

This clinical clerkship must also develop in the student a sense of personal responsibility to patients for their drug therapy.

Requirements:

1. Role model practitioners must be operational in all areas where the required clinical clerkship is conducted.

2. The required clinical clerkship should be a full-time experience of a minimum of 40 hours per week. No required didactic courses should be conducted which draw the student away from the patient care environment. Students may take elective didactic courses if these do not interfere with their clinical experience.

3. The required clinical clerkship should be composed of the following:

   Inpatient Services: General medicine and sub-specialities--10 to 12 weeks (400-480 hours); pediatrics--4 to 5 weeks (160-200 hours).

   Ambulatory Care Services: (Such as primary care clinics, family practice specialty clinics, etc.)--10 weeks (400 hours).

   Psychiatry Services--both inpatient and outpatient, 4 to 5 weeks (160-200 hours).

Remarks: There was differing opinion among Workshop Groups and Conference participants concerning whether clerkships involving a general surgery service should be part of the required clinical clerkship component in lieu of psychiatry services. The major argument advanced in support of surgery services was that the surgery patients constitute one of the largest patient populations

and a required clerkship should, thus, be included in order to provide the appropriate breadth of experience. The counter argument went along lines that general medicine clerkships provided most of the same experiences and that surgery patients per se were not sufficiently unique to justify a required clinical clerkship. The argument advanced for psychiatry clerkships was that psychiatric disorders and the use of psychotropic drugs are so prevalent in society that the "complete Pharm.D." should have experience in this area.

Selective-Elective Clinical Clerkships

Goals: These clinical clerkships should develop the student skills in areas of specialty interest. Specific objectives should be established by the preceptor prior to the student entering each area.

Requirements:

1. Experiences should be a minimum of 160-200 hours each. There should usually be four experiences.

2. Students should take as wide a variety of experiences as possible.

3. Presence of a role model is desirable in each area of subspecialty practice, but is not an absolute requirement. However, there must be a preceptor responsible for, and supervising, the student's activities at all times.

4. Examples of areas recommended for elective clerkships are: cardiology, infectious diseases, nephrology, hematology, oncology, gynecology, neurology, surgery, and emergency services. Long term care facilities, drug information service and pharmacokinetics laboratories are also potential sites for elective clinical clerkships. This list is not considered as all inclusive and other types of electives may be considered.

Summary of Time Distribution in Clinical Clerkships

Introductory clerkship	200 hours
Required clerkship	1120-1240
Elective clerkship	800
Total:	2120-2240 hours

Process of the Clinical Component:

During the clinical clerkship, students should not receive compensation for their activities. Compensation carries the danger of placing excessive emphasis on a service component at the expense of the educational component of the clerkship.

Certain drug distribution activities (including dispensing, supervision of technicians, preparation of IV fluids and other technical functions) are more appropriately covered in other courses in the curriculum, including

externships, and are not recommended to be part of clinical clerkships of the Doctor of Pharmacy program.

Externships qualify as clinical clerkship courses only if they meet the specific criteria for clinical clerkships.

The clinical experience should include direct patient contact. The student should have interactions with the patient which include assessment of health status and the provision of patient education.

The student should have access to the complete medical record, including results of laboratory tests, physical examination, diagnostic and progress notes, vital signs and medication orders.

The student is expected to interact with other health professionals in the clinical area via consultation, participation in rounds and conferences, in-service education and other activities related to patient care and teaching.

The student should regularly interact with the preceptor throughout his/her clerkship. The interaction with the preceptor should include:

Review: The preceptor must review all student recommendations and presentations concerning patient care prior to their implementation.

Teaching: The preceptor must function as a teacher who can review with the student the important points of a particular problem and direct the student in self-study.

Evaluation: The preceptor is responsible for the ultimate and day-to-day evaluation of student performance. There should be an on-going effort throughout the clerkship to help students improve in weak areas.

Remarks:

The purpose of the selective-elective clerkships is to provide breadth to the student's program. There is not an intent to use these to specialize in one area of professional practice. Thus, students should not be allowed to spend all of their elective time in one professional practice area.

The recommendation of the Workshop Group concerning the amount of time to be devoted to clinical clerkships is in excess of the 1500 hour figure specified in the "Tentative Guidelines". The consensus was that the minimum time needed to develop the appropriate level of clinical competency is closer to 2000 than 1500 hours. However, those schools which have developed detailed behavioral objectives to describe their clinical experience programs and which have evaluation mechanisms adequate to assure achievement of these objectives should not necessarily be held to the recommended time distributions.

Although it is recommended that formal didactic coursework not occur during the required clinical clerkships, this should not preclude the candidate's participating in seminars, conferences and other teaching sessions which take place in the patient care environment. The major intent is to avoid withdrawing the student from the patient care environment for long periods of time or at times of the day when critical learning experiences occur in the clinical setting.

Comments from the General Session

Concern was expressed by some Conference participants over use of parameters of time to define the extent of the clinical clerkship component. It was recommended that a competency-based approach would be better. Workshop members agreed, but pointed out that they started from the point of practicality and the present state of the art. Use of time specifications seems the only way, for the immediate time, to describe relative emphasis for clinical clerkships. It is recommended that the hour distributions be considered as general guidelines.

It was noted that some baccalaureate programs feature similar clerkship emphasis areas. Doctoral education differs in the endpoints achieved; i.e., degree of student responsibility and sophistication of experiences.

MISCELLANEOUS CURRICULUM CONSIDERATIONS

Outpatient and Ambulatory Care Experiences

Charge: Page 7, lines 11-17, of the "Tentative Guidelines" state, "although both a clinical clerkship and externship are required in each curricula, the major experiential emphasis of the doctoral program should be in patient care areas of hospitals and related clinical facilities. Externship experience in outpatient areas should comprise the minority of experience and should involve closure or longitudinal experience, as well as research in ambulatory patient care."

This workshop should develop recommendations for the types of outpatient care activities with which the doctoral candidate should be made familiar. Should the "guidelines" place more emphasis on ambulatory outpatient care? If so, what are the minimal abilities which should be developed and experiences which should be provided?

Recommendations

Accreditation guidelines should place greater emphasis, relative to the present "Tentative Guidelines", on the importance of outpatient and ambulatory care as a component of the Doctor of Pharmacy curriculum.

The following are offered as quidelines for the outpatient and ambulatory care component of the clinical curriculum:

Potential Sites: Hospital outpatient clinics; i.e., adult medicine, pediatrics, emergency room and subspecialty clinics; Health Maintenance Organizations; skilled nursing facilities; community health service facilities - i.e., outpatient mental health, drug abuse, student health; family practice centers (group practice); community pharmacies; home health care.

Criteria for Site: Presence of a role model, availability of patient records, interaction with other health care professionals, availability of information resources, availability of opportunity for interaction with patients.

Necessary Experiences:

Development of Drug Histories -- evaluation for adverse drug reactions, evaluation of patient compliance, degree of drug use

Evaluation of patient records in presence and absence of complete clinical data

Development of Drug Therapy Regimen

Development of Monitoring Parameters

Evaluation of Drug Therapy -- success or failure, follow-up responsibility, therapeutic alternatives

Patient Education -- counselling involving total therapeutic program in relation to disease state, diet, prescription and OTC products, diagnostic agents, and medical-dental-surgical appliances

Interprofessional Communications -- drug information services, in-service education

Drug Utilization Review

Continuity of Care Responsibility

Triage

Public Health Service (optional)

Service Clubs, Schools, etc.

Development of Clinical Research in Outpatient Environment (optional)

Skills to be Attained: Communication techniques (interviewing techniques, interprofessional dialogue, public speaking and writing, special techniques -- i.e., hostility, hysteria, confabulation, poor historian); problem identification and solution; collection and evaluation of subjective and objective patient data; correlation

between patient, disease state and drug therapy; information retrieval.

Minimal Time Requirements: Ideally, should be based on competency characteristics. Minimum of 400 hours (equivalent to 10 weeks full time) in at least 2 different ambulatory settings, one of which must be an adult or pediatric comprehensive clinic.

Comments from General Session

It would be important to include some emphasis on the promotion of "wellness" and preventive medicine in this clerkship experience. This should include considerations of both primary and secondary methods of preventing illness.

Some Conference attendees questioned the desirability of utilizing community pharmacies and home health care programs in the Doctor of Pharmacy program on the basis that these are fundamental to baccalaureate programs, and such practice need not be duplicated in the Doctor of Pharmacy curriculum.

Student Responsibilities and the Degree of Supervision in the Clinical Component of the Curriculum

Charge: What is the appropriate degree of responsibility for decision making during the clinical experience program? How much personal responsibility for patient care should be assigned to the student? What is the appropriate degree of supervision which should be given the doctoral candidate?

Recommendations

The Workshop Group developed no quantitative recommendations relative to this charge. The following recommendations outline the general philosophy relative to student responsibilities:

1. Close supervision should exist during the introductory and beginning stages of the required clinical clerkships.

2. As the clinical component progresses, the student should be required to assume progressively greater and greater responsiblity which increases from observation, continuing through participation, to independent activity at a point near termination of the program.

3. The transition to progressively greater responsiblity must be governed by the student's progress as measured by: a) end of process supervision, b) end of task supervision, c) end of day review.

4. An immediate review mechanism must exist for all patient care related actions taken by the doctoral candidate. This implies ready access to a preceptor at all times.

Editorial Note: Sections on Competencies and the Clinical Curriculum should also be reviewed for statements concerning student experiences in patient care related activities.

Relationship of the Clinical Component of the Curriculum to Post-Doctoral Residencies

Charge: The relationship between the clinical component of the Pharm.D. curriculum and post-doctoral residencies needs to be brought into focus. What should be the purpose of the pre-doctoral experience as contrasted to the residency?

Recommendations

The pre-doctoral clinical experience should be designed to provide the student the education necessary to function as a generalist in the clinical applications of drug knowledge. The post-doctoral residency should be reserved for expanding the fundamental clinical experience and for specializing in specific areas of clinical practice. The post-doctoral resident should be allowed to function without immediate review and supervision whereas, the Pharm.D. candidate's actions must be subject to immediate review.

The post-doctoral residency should allow opportunity to initiate and develop new information via the conduct of clinical research which is more comprehensive in nature than the research projects of the pre-doctoral program.

Special skills needed for teaching in the formal and informal environments of classrooms and patient care areas should be developed during the post-doctoral residency.

Remark: Conference participants strongly indicated the necessity to clearly identify the fact that post-doctoral residencies should not be used to replace the clinical component of the Doctor of Pharmacy curriculum. In the above recommendations, then, the post-doctoral resident is assumed to have previously completed the clinical component of the Doctor of Pharmacy curriculum described in proceeding sections of this report.

Comment from the General Session: The post-doctoral residency should not be required of all Doctor of Pharmacy program graduates. The residency should be elective for those persons seeking specialty training or desiring careers in teaching and/or clinical research.

Social, Behavioral and Anthropologic Aspects of Doctor of Pharmacy Education

Charge: Page 7, lines 5-6, of the "Tentative Guidelines" state, "Disease states and therapeutics must be studied from a holictic view including social, behavioral, and anthropological implications." What would be appropriate indicators that this occurs in the

Pharm.D. curriculum? What types of courses might be needed? What experiential programs should be available?

Recommendations

Four didactic courses are recommended to appropriately achieve the objectives outlined in the "Tentative Guidelines". It is to be noted that these topic listings below are examples, and are not to be considered as all inclusive of content of these courses.

Medical Sociology - Factors in illness (social group communications, death and dying, human sexuality, abnormal psychology, social environment effects, disease versus illness); socialization (acceptance of the student as part of the health team, acceptance of the student as being a pharmacist, motivation and learning).

Professional Communication Skills - Terminology; techniques (verbal presentation - group and personal, written skills, group dynamics, listening); problem solving; decision making.

Note: These skills should be reinforced in all courses and clerkships of the Doctor of Pharmacy program.

Health Care Systems - Organization, financing, cost, quality, manpower, roles, facilities, legislation, technology, politics, access to health care, drug utilization and peer review.

Public Health and Community Medicine - preventive medicine, mortality and morbidity, epidemiology, international health.

The indicators for the didactic portions should include syllabi, faculty, and facilities necessary to teach the program.

The didactic portion should be correlated with the clinical experiences as the student has contact with other professions, including the social worker, physical and occupational therapist, clinical psychologist, clergyman, nurse, dentist, and physician.

The experiences should be related to pharmacy practice outcomes. The experiences may include: ambulatory settings(HMO, nursing home, rural health, visiting nurses association); societal settings (mental health, free clinic, alcohol and drug abuse, mental retardation, screening centers); acute inpatient care settings.

Remarks:

Inclusion of a course on ethics was considered by the Workshop Group, but it was not included in the recommendation since there was divided opinion concerning need.

Many aspects of the four recommended courses are commonly covered in baccalaureate programs; and, therefore, may not appear as such in the Pharm. D. curriculums. It is the intent of the recommendations that these topics be covered within the student's total pharmacy education and that they be reinforced and applied in the Doctor of Pharmacy program.

EVALUATION AND STUDENT QUALIFICATIONS

[Recommendations for this section are derived from the reports of Workshop Groups 6-A and 6-B].

EVALUATION OF STUDENT PERFORMANCE

Charge: What should be evaluated and what types of evaluative mechanism should be employed?

Recommendations

Two Workshop Groups addressed this topic. Their recommendations, while similar in some respects, presented different approaches to the evaluation of student performance. The first, more addresses the question - what should be evaluated? The second, emphasized process and is based on the assumption that behavioral objectives have been defined at all levels of the curriculum. Since it was not possible to combine the two recommendations, both are included for completeness and to assure a comprehensive coverage of the topic.

Editorial Note: The reader should keep in mind that the workshop groups addressing this charge did not have available the list of expected competencies developed in the first section of this report. This was not the ideal situation since what is to be evaluated must be the achievement of program objectives as outcomes of instruction (behavioral objectives). The reader should be aware of this point in studying Scheme A and Scheme B, which follow. The group which developed Scheme A derived a set of terminal behaviors around which to present a specific set of evaluation mechanisms. These behavioral expectations differ somewhat in educational intent from those derived by other workshops specifically charged to develop the competency statements. Scheme A is thus directed to a set of program objectives. Its major value is in listing some possible evaluation techniques. On the other hand, Scheme B presents a more general approach based around a set of assumptions which are applicable to whatever program objectives have been stated. Samples of evaluative approaches and techniques are presented. Because Scheme B presents a more generalizable approach, it may be more helpful for describing an evaluation process for the Doctor of Pharmacy curriculum.

Scheme A

This workshop first attempted to establish terminal behavior which is necessary for a Pharm.D. graduate and to then use these terminal behaviors as an answer to what should be evaluated. For each of these terminal behaviors, it was realized that there were a large number of basic and intermediate behaviors which the curriculum and each course must define as their goals and objectives and which the student must possess to achieve the terminal behavior.

For each behavior, it is a must to define what is accepted versus non-accepted performance. This delineation should then be shared with the student along with the goals and objectives and related terminal behavior expected for each area.

The evaluative process attempts to look at the individual's ability to meet the stated objectives. This attempt includes measuring what knowledge the student possesses and his/her ability to perform given tasks or meet stated objectives. The measuring of these behaviors can occur through written or verbal responses and ability to complete a given task. This task may be in the form of a decision that must be made. These evaluations must not be inferred; rather, they should be stated in terms of readily observable criteria.

Four terminal behaviors are identified. The student must demonstrate ability to:

1. Promote rational drug therapy.

2. Integrate the psycho-socioeconomic aspects of patient care into professional practice.

3. Identify problems and conduct clinical research.

4. Be responsive to the changes in health care delivery policies and systems.

For each category of behavior, specific knowledge and skills are necessary. To achieve these terminal behaviors, the student must demonstrate competency in the following areas. The items listed under each skill are not intended to be all-inclusive, but to only serve as examples.

Promote Rational Drug Therapy:

Cognitive Skills: Definition of therapeutic objectives and end-points based on a stated patient problem; detection of drug-induced problems; evaluation and application of drug literature, and selection, initiation and assessment of drug therapy.

Psychomotor Skills: Physical assessment techniques; medication administration and instrumentation; e.g., defibrillator, resuscitators, computer terminals, pH meters.

Communicative Skills: Data gathering (profiles, interviews); documentation (POMR, etc.); and education of other health-care practitioners and health consumers.

Integrate the Psycho-socioeconomic Aspects of Patient Care:

Cognitive Skills: Influences of internal and external environment,

e.g., psychological - death and dying, childbirth; social - cultures, customs, mores; economic - third party related to social economic status.

Psychomotor Skills: Non-verbal communications; e.g., body language.

Communicative Skills: Individualized instruction to meet particular patient needs through audio-visual aids.

Identify Problems and Conduct Research:

Cognitive Skills: Defines problem, uses statistical techniques.

Psychomotor Skills: Selection and use of appropriate experimental instruments and techniques.

Communicative Skills: Document preparation and verbal defense.

Responsive to Changes in Health-Care Policies and Systems:

Cognitive Skills: Knowledge of current health regulations; awareness of different health-care delivery systems.

Communicative Skills: Use of referral systems; interface with legislative processes.

Types of Evaluative Mechanisms: The curriculum should be designed to meet the four previously stated terminal behaviors. Each area in the curriculum should attempt to meet some portion of these terminal behaviors that have been stated. The student must be evaluated to assess the cognitive, psychomotor and communicative skills that she/he must possess for successful completion of these particular segments. An analogy can be made to a chain, in which each course represents a link. The strength of the chain is dependent upon the strength of each link and its position in sequence. The student cannot proceed to the next course or area unless she/he successfully completes the previously outlined course. The student can be tested for possession of the facts using written and verbal exercises. The student must also be evaluated for ability to comprehend these facts. This can be done through written and verbal methods and through situation-type exercises where the student must complete tasks by making decisions. The student must also be able to apply facts to the environment in which these will be used. For these practical experiences, seminars, performance in clinical settings, conferences with peers and other health care professionals, interviews and discharge summaries can be employed. Each of these evaluations must specify expected behaviors and acceptable behaviors. Upon successful completion of the individual evaluations, a comprehensive evaluation mechanism must be employed. This comprehensive examination should use all of the methods previously described and measure the student's ability to achieve the terminal behaviors

defined. Written and verbal examinations should be used along with task-completion methods where an audit of performance can be undertaken by the testing group. An external examination by pharmacists experienced in clinical practice could be employed to survey acceptability of performance.

Scheme B

The group interpreted its charge as the development of recommendations as to which mechanisms are to be used to evaluate student competencies. In light of this, certain basic concepts are proposed:

1. Evaluation should be defined in its broadest sense to include use of evaluative tools in the educational process to measure the attainment of goals and to guide instructional effort.

2. All evaluative mechanisms should be utilized as much as possible in each segment of the curriculum.

3. Evaluative mechanisms should be cumulative at every level.

4. Evaluative techniques should have a consistency of application in all components of the educational structure.

5. As a synthesis of points 1 and 4, above, the educational system should be modified by adjustments deemed necessary following analysis of output from the evaluative mechanisms.

6. Subjective assessment mechanisms are included for completeness, but are to be viewed as a "stop-gap" measurement technique and objective measurement techniques should be developed whenever possible.

7. Evaluation instruments should assess terminal behavior as much as is possible.

Evaluation should be designed to primarily measure the terminal behavior dictated by the competency based curriculum. Evaluation mechanisms suggested below are to be thought of as mechanisms to assess completion of the terminal behavioral objectives. However, the evaluative mechanisms listed below are also to be utilized to assess student progress through the curriculum utilizing either partial completion of the terminal objectives or total completion of less stringent objectives as milestones toward the completion of the full complement of terminal objectives. Therefore, these evaluative mechanisms pre-suppose a defined set of terminal behavioral objectives.

Terminal behaviors involve a number of facets of performance that can be measured. These include: communicative skills (including teaching), factual knowledge, affective characteristics, analytical abilities, and ability to interact within an organizational setting with all health professionals to accomplish work.

Evaluative mechanisms to be applied to these areas are:

Communication Skills (including teaching)

Verbal Skills -- The measurement technique is observation. Assessment is made utilizing: objective criteria; e.g., predetermined behaviors or criteria of performance.

Writing Skills -- (reports, drug literature evaluations, chart roles, papers, etc.) -- Evaluation is based on pre-determined criteria relating to: factual content, proper English writing form and use of medical terminology; organization; clarity, brevity, aptness of thought; and logic of thought and relevance.

Factual Knowledge

Standardized written examinations and verbal examinations -- These should be norm referenced with pre-determined percentage scores on examination of factual information established as acceptable.

Spontaneous verbal examinations -- The measurement technique is observation. These are utilized to assess student's daily verbal interactions for factual content. The mechanism of evaluation is objective, and is determined by the student's ability to support verbal statements with literature referenced documentation.

Verbal presentations (seminars, case presentations, reports)-- The mechanism of evaluation is the same as above for verbal examinations.

Affective Characteristics (psychological characteristics and personality qualities)

The measurement technique is observation or prepared instruments such as psychological tests. The mechanism of evaluating should be a scalar set of behaviors such that each behavior or quality is expressed as a continuum on a scale from the best to the worst, with scale division defined in terms of behaviors. Observation and evaluation should be done by multiple observers.

Analytical Abilities

Research -- The measurement technique is evaluation of student performance in an assigned research project. Research methodology should be evaluated utilizing criteria identified under Communicative skills - written; results may be evaluated utilizing criteria defined under Communicative skills - written, and utilizing verbal examination format.

Problem identification and problem solving -- Measurement techniques include:

Contrived situations (case studies) where performance is evaluated utilizing mechanisms defined under Communicative skills - verbal and written. Predetermined performance criteria must be established for problem identification and solving.

General performance audits where the student's ability to perform in the practice environment is measured utilizing predetermined behavioral objectives which become progressively more difficult.

Specific performance audits of both product and process. Product audits are made by evaluating at an instant in time the outcome(s) of a student's problem solving effort utilizing a predetermined set of objectives. Process audits require day-to-day evaluation of the student's performance based on predetermined criteria for "acceptable process" such as algorithms for treatment and acceptable techniques of monitoring patients which permit problem identification. The student's decision making capability and capacity to function independently should be evaluated as part of the performance audits.

Ability to Interact with Health Professional Within an Organization to Accomplish Goals

The measurement technique is observation. Student performance is assessed utlizing predetermined sets of behavioral objectives.

Remarks

Scheme A stresses cognitive, psychomotor and communicative ability. The affective domain has not been emphasized. This was done because the workshop group felt that the ability to measure attitude is now only in the very formative stages. It is not implied within Scheme A that communication skills are equivalent to the affective domain. The workshop group which developed Scheme B considered that the affective domain should be included in the behavioral objectives since it was thought to be inseparable from behavior. This group felt that effect could be measured, but that this would require measurement in a situation-dependent way using predetermined behavioral objectives.

CRITERIA FOR ADMITTING STUDENTS

Charge: Recommend criteria for accepting students into Pharm.D. programs.

Recommendations

Criteria vary depending upon whether the Doctor of Pharmacy degree is the only degree offered by the school or is presented as either a post-baccalaureate or an elective variant from the Bachelor's program. The following should be component parts of the evaluation process relative to admission of students to the Doctor of Pharmacy program. These must be applied consistent with institutional policy and procedure for admitting students to degree programs.

1. Previous College Record:

   a. Academic performance (e.g., G.P.A., transcript, honors).

   b. Clinical performance (e.g., projects, grades in clinical courses).

   c. Organizational work (e.g., extra-curricular activities).

2. Standardized tests of G.R.E. type.

3. Letters and recommendations.

4. Written essay.

5. Personal interview.

Remarks

The importance of rigorous criteria for admitting students to doctoral programs is emphasized. The present "state of the art" is that suitable criteria have not been proven in health science education. Neither group felt that there was sufficient time during the workshop sessions to adequately consider this charge. The recommendation relative to admission criteria should therefore be regarded as in need of further development.

FACULTY AND STAFF

[Recommendations for this section are derived from the report of Workshop Groups 1-A and B.]

Charge: Recommend the types of faculty, by discipline, which should be available to the overall program--including basic science and applied (clinical) areas.

Qualifications of various types of clinical faculty should be recommended. This includes academic preparation, clinical skills, discipline or emphasis-area and professional maturity considerations.

Types and qualifications of faculty-practitioner-educators from other health science disciplines should be recommended.

To what extent is it desirable that the clinical faculty person be practicing in patient care-related functions in order that the practitioner-educator concept be maintained?

Recommendations:

Types of Faculty

In addition to those faculty needed to teach the basic courses required of all pharmacists, faculty should be available to provide advanced-level instruction in the following topic or discipline areas. (It is recognized that some of these may also teach courses in the baccalaureate program when both bachelor and doctoral degrees are offered by a school.) The faculty should include both basic scientists and clinicians.

1. Pharmaceutical Sciences--Pharmacokinetics and biopharmaceutics, pharmaceutics, and radiopharmacy (desirable, not required).

2. Biomedical Sciences--Pathophysiology, biochemistry (clinical), and pharmacology and toxicology (clinical).

3. Clinical Pharmacy--Specialists in the practice areas specified for clinical clerkships, and drug information.

4. Other Health Science Clinicians--Medicine, dentistry, nursing, and allied health.

5. Other--Biostatistics and experiment design, social and behavioral sciences, health care and pharmacy services administration, public health, and education evaluation (desirable).

It is considered desirable for the pharmacy school to have a deciding role with respect to faculty and course content supplied by other academic units to the Doctor of Pharmacy program. It is recognized that this will be influenced by institutional policy. Joint appointments of faculty between the pharmacy school and other departments is desirable.

Qualifications of Faculty

Basic and Pharmaceutical Sciences: In addition to possessing qualifications appropriate to their scientific discipline, basic science faculty should be knowledgeable about goals and objectives of the Pharm.D. program; should be sufficiently conversant with the programs to apply basic sciences principles to patient care problems; should have some clinical involvement commensurate with the extent of their teaching responsibilities in the Pharm.D. program; and should have continuous interaction with the clinical faculty.

Faculty from other Health Science Disciplines: Teachers from other health science disciplines will usually be practitioners-educators holding university appointments or eligible to do so.

Clinical Pharmacy Faculty: The Clinical Pharmacy faculty person should possess an advanced educational background to at least the professional doctorate or master's degree level, or the equivalent. This should include both academic preparation and clinical education and training. Completion of a residency which emphasized the clinical aspects of pharmacy practice, or equivalent clinical experience, is considered desirable.

The academic and professional experience background of the clinical pharmacy faculty person should have provided the following important qualities:

a. Especially strong knowledge of principles of biopharmaceutics and pharmacokinetics and their application to the sick patient. The academic background should include laboratory work.

b. Excellent knowledge of pharmacology and therapeutics.

c. Working knowledge of biostatistics and experiment design. The academic preparation should include a graduate level course in biostatistics.

d. Excellent knowledge of principles of pathophysiology. The academic background should include a strong course in patho-physiology.

e. Good background in the socio-psychological aspects of disease and of health care.

f. Familiarity with the thought processes through which the physician arrives at his diagnosis and the processes whereby specific drugs are selected for the treatment of patients.

g. Experience in counseling patients, physicians, and other health personnel on the safe and appropriate use of drugs.

h. Experience in gathering, analyzing, interpreting and disseminating a wide variety of drug information from various recognized sources.

In addition, the clinical pharmacy faculty person should demonstrate the ability to interpret, collate and analyze clinical data and apply this along with his/her knowledge of drugs to the patient care process; to work and communicate effectively with patients and other health care professionals; to organize and supervise the providing of pharmaceutical services and/or integrate clinical aspects of drug use with more traditional pharmaceutical services; and to conduct or participate in research. The clinical faculty person should be active in his/her profession and be conversant with trends and issues in contemporary practice and education. He or she should demonstrate an ability to satisfy institutional criteria for faculty appointments and promotions.

The clinical pharmacy faculty should be practitioners with regular responsibility for care of patients. The time relationship between patient care and other responsibilities should be approximately 50+20%.

It is specifically noted that use of clinical pharmacy residents as primary faculty for Doctor of Pharmacy candidates is not acceptable. This should not preclude the involvement of post-doctoral residents in the teaching process, however.

Clinical Pharmacy Faculty - Group Considerations: In addition to the personal qualifications described in the previous section, the following should apply to the clinical faculty when considered as a group:

1. Experiences and involvement in the patient care setting, including patient service responsibilities should be on-going.

2. The faculty should include persons experienced both in providing patient care and in teaching.

3. The faculty should include a sufficient number of persons with specialized knowledge so that the whole spectrum of required and elective clerkships can be provided.

4. Faculty assignments and expectations should provide for a balance of teaching, service, administrative responsibility, and research.

5. The clinical faculty should be accorded full faculty privileges.

Remarks:

No recommendations are made concerning desirable student/faculty ratios. The reason for this lies in the difficulty of separating service and teaching responsibilities as they contribute to education of the student. Since service/teaching responsibilities of faculty vary considerably among programs and even within programs, there is little basis for establishing a recommended student/faculty ratio. Also germane to the student/faculty ratio question is the fact that new programs often draw heavily on medical faculty. As the program matures, the number of clinical pharmacists on the faculty should increase with a resultant change in student/faculty

ratios. In the case of a new program, it is important that there probably exists a "critical" mass of clinical pharmacist faculty which must be present from the beginning. These should probably equate to those persons required to provide role models for the essential elements of the clinical clerkship component of the curriculum.

Editorial Note: The reader should note the statement on page 8, item 4, under Requirements of the Introductory Clerkship, which recommends that "not more than four students should be assigned per faculty member."

Comments From the General Session:

With respect to the degree qualifications of clinical pharmacy faculty, the Pharm.D. degree should be considered the "norm".

Clinical pharmacy faculty providing instruction in specialty areas should be Board certified when such certification programs become a reality.

It is important that the primary clinical faculty give evidence of scholarly activity. This might be research or it might be other creative and original work. Performance only as teachers and practitioners without evidence of scholarly activity should be considered as not acceptable for faculty of a doctoral level program.

The recommendation that basic science faculty be able to apply their discipline to patient care is subject to challenge. The "bridging function" between basic science and patient care might more appropriately be done by clinical faculty. The basic science faculty must be thoroughly familiar with the program goals, however.

THE SERVICE ROLES OR FUNCTIONS

Charge: Establish recommendations concerning those service functions and/or teaching models which must be present in order to adequately support a Pharm.D. program.

Maturity and utilization factors should be considered. For example, mere presence of a Drug Information Center may not be sufficient if it is not utilized by health professionals with any frequency.

Services, professional functions and facilities might be prioritized according to those which must be present if a Pharm.D. program is offered, those which would be desirable and those needed only if specialty training is provided.

Physical and financial resources needed to provide, conduct or otherwise support these functions might be given consideration.

ASSUMPTIONS AND DEFINITIONS

It is assumed that the Doctor of Pharmacy graduate is not a specialist beyond his unique knowledge and abilities as a clinical practitioner. It is noted that residencies fulfill specialization requirements.

Service functions are defined as those things necessary to support the curriculum. They may or may not be done by a pharmacist.

Role models are defined as those persons who perform some service or functions intended to serve as examples to Doctor of Pharmacy students.

RECOMMENDATIONS:

General Requirements

The following general conditions should exist in support of a Doctor of Pharmacy program:

1. An environment which features interdisciplinary education.
2. A sharing of financial support of service and education resources.
3. A minimum of one faculty member assigned to each essential role model.
4. Institutional and ambulatory facilities which meet legal and accreditation standards. These facilities can be within one medical center, located within several institutions, or in sites removed from the immediate vicinity of the school of pharmacy. It is not only essential that these facilities be available to the program, but they should be actively utilized in support of Doctor of Pharmacy education.

Types of Services

Where necessary, there should be affiliation agreements between the school and institutions serving as teaching sites. Such agreements should include statements of liability and responsibility. The following service units should be available for use in instruction:

Pharmacy Services - These should be well managed and should include a unit dose drug distribution system, a sterile products program, intra and interdepartmental inservice education and outpatient pharmacy services. The latter should include drug therapy monitoring and patient counseling.

Remark: While it is ideal that every institution utilized by the teaching program possess exemplary pharmacy services, this is not considered mandatory. Throughout the total spectrum of teaching institutions, there should be available somewhere the components of an exemplary pharmacy service.

Drug Information Services - These should be responsive to referrals for patient-specific information concerning use of drugs in therapy. The services provided should include: 1) drug literature retrieval, evaluation and reporting, and 2) poison information service (considered to be desirable, but not essential to conduct of a Doctor of Pharmacy education program).

Health Sciences Library

Computer Center

Direct Patient Care Services - The following should be available:

Acute, short term care facilities with the following services available to the education programs: medicine services (including subspecialty areas and geriatrics); pediatric services; surgical services; and psychiatric services.

Remark: There was divided opinion among workshop participants concerning the relative importance of surgical services and psychiatric services. Some thought surgery services were essential while psychiatry would be desirable, but not essential. Others held the reverse opinion.

Chronic, long-term care facilities, including nursing homes. (Considered to be desirable, but not essential to conduct of a Doctor of Pharmacy education program).

Ambulatory care facilities which include: primary care and specialty clinics; community mental health centers; community pharmacies; and home health care services. The latter three facilities are considered desirable, but not essential to the conduct of a Doctor of Pharmacy education program.

Indirect patient care services - the following should be available: clinical pharmacokinetics laboratory, clinical laboratory, and health care administration. Clinical pharmacology research service, nuclear pharmacy, and social services are considered desirable, but not essential to the conduct of a Doctor of Pharmacy education program.

Role Models

Characteristics - persons serving as role models should exhibit the following characteristics:

1. They are practitioner-educators.
2. They continue to practice in the absence of students.
3. They practice the team care concept of health care.
4. They demonstrate measurable and continuing professional growth.
5. They demonstrate clinical research capabilities.
6. They include drug therapy monitoring and therapeutic assessment as part of their practice.

Role models available:

1. Clinical Pharmacists - Adult ambulatory care; adult acute care; adult intensive care, and pediatric care. Also considered desirable, but not essential to the conduct of a Doctor of Pharmacy education program are geriatric, psychiatric/mental health, and long-term chronic care.
2. Drug Information Specialist
3. Clinical Pharmacokineticist
4. Primary Health Provider (considered desirable, but not essential to the conduct of a Doctor of Pharmacy education program.)
5. Nuclear Pharmacist (considered desirable, but not essential to the conduct of a Doctor of Pharmacy education program.)

Remark: Regardless of the specialty area of clinical pharmacy practice, certain functions are common among the role models. As part of their practices, clinical pharmacy role models should be directly monitoring therapeutic response, consulting with other health care practitioners, detecting adverse drug reactions, optimizing dosage regimens and conducting research. They should be developing drug therapy regimens and implementing drug therapy protocols when needed.

Comments From the General Session:

The recommendation that there should exist a sharing of financial support for service and education resources was challenged. It may be argued that it is the presence of, and quality of a service or role model that is critical to the educational program. Intrainstitutional policies regarding financial support of programs are too variable to be subject to the accreditation process. The counter argument is that presence of institutional support lends credibility to the role model as a valuable patient care activity. The importance of role model credibility is considered to affect student acceptance and may reflect on his/her eventual ability to apply concepts of the role model to practice. This issue was unresolved by Conference attendees.

Some services and/or role models utilized by the program should be based outside the university medical center environment. Students should be exposed to health care delivery in the non-academic institutional setting.

Consideration should be given to whether the Doctor of Pharmacy program should de-emphasize activities relating to management of outpatient psychiatric patients as well as patients with chronic illness. Management of such patients may be more appropriate to the educational background of baccalaureate degree level practitioners.

REMARKS AND RECOMMENDATIONS OF THE STEERING COMMITTEE

Many of the recommendations in this report emphasize those more readily observable or measurable parameters of Doctor of Pharmacy programs such as course titles and clock hours of instruction. This was done purposefully, in order to provide the American Council on Pharmaceutical Education, and other users of this report, a set of recommendations which could be immediately useful in evaluating Doctor of Pharmacy programs. Detailed lists of terminal competencies to be possessed by the graduate have not been developed. The Steering Committee strongly emphasizes the need to continue to maintain progress in refining the guidelines toward better defining the basic or minimal competencies expected of the Doctor of Pharmacy graduate in terms of behavioral objectives. Definitive methods of evaluating student progress in achieving these competencies must be developed. Development of national standard exams in both basic sciences (e.g., pharmacology, pharmacokinetics and biopharmaceutics) and clinical areas (e.g., therapeutics, clinical pharmacokinetics) to be utilized by the ACPE in program evaluation and by schools as a self-assessment mechanism should be given careful consideration.

The Conference format forced the key elements identified by the Steering Committee to be dealt with separately. As a result, each section of this report tends to stand by itself as a discrete entity. However, in fact, there must be a strong interaction between these elements in the doctoral program. An appropriate blending of these elements in such a way that they complement and reinforce each other is the key to "building" a doctoral program which is of high quality.

It is recommended that an ongoing review and upgrading of the"guidelines"

be made consistent with further growth and development of doctoral programs. The American Association of Colleges of Pharmacy should work closely with the American Council on Pharmaceutical Education toward such an endeavor. Strong consideration should be given to repeating this conference, on a biennial basis, until doctoral programs have reached their maturity and the need for further and continual refinement of the accreditation guidelines has diminished.

Careful reading of this report leads to the impression that most conference participants were considering requirements which the doctoral program should include in addition to those of the traditional baccalaureate program. Stated another way, the philosophy of the "add-on" format seems to prevail. Perhaps this is because most currently operational programs are designed to accommodate students who have already acquired the baccalaureate. Thus, many of the recommendations in this report may not be sufficiently all-inclusive when related to those programs where the Doctor of Pharmacy degree is the only one offered for the total educational process.

This report contains several inconsistencies with respect to the need, importance and desirability for student involvement with contemporary drug distribution systems as part of the doctoral program. There was some, but not major, discussion of this issue during the General Session. It is our impression that a majority of participants accept the concept that some connection with the hospital pharmacy drug distribution systems should be mandatory, and this is clearly implied by several recommendations from the workshops. However, a significant number of persons appeared to feel that the primary focus of doctoral programs should be on the direct patient care process and that traditional pharmacy service involvement is an unnecessary distraction. Unfortunately, the issue did not develop to the point of debate at the Conference. The reason is not apparent for this appears to be a very fundamental issue concerning content of doctoral programs. Thus, this remains a poorly identified and not resolved issue by this Conference.

Elsewhere in this report, it is noted that one conference participant pointed out the danger of assuming that today's baccalaureate programs provide a common academic base for all students. Until this is true, it will be difficult to achieve uniform quality and ability among all doctoral graduates. It is recommended that the American Council on Pharmaceutical Education consider revising its guidelines for accrediting baccalaureate degree programs in order to provide clearer guidance to the colleges and to assure some degree of uniformity of program quality. Perhaps a national conference of pharmacy educators similar to this conference should be convened for purposes of developing recommendations for content of baccalaureate programs.

APPENDIX I

ROSTER OF CONFERENCE PARTICIPANTS

AACP CONFERENCE ON GUIDELINES FOR PHARM.D. PROGRAMS

ROSTER OF CONFERENCE PARTICIPANTS

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The following persons also attended the Conference as observers, rather than as active participants:

Dr. Allen J. Brands, Chief Pharmacy Officer
Public Health Service

John F. Schlegel, Pharm.D.
Director, Office of Student Affairs
American Association of Colleges of Pharmacy

Dr. Warren E. McConnell
Director of Professional and Educational Services
American Society of Hospital Pharmacists

Mr. Joseph G. Shalinsky
Secretary, Kansas State Board of Pharmacy
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Dr. Warren E. Weaver, Dean
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Representing the American Council on Pharmaceutical Education

APPENDIX II

LIST OF CHARGES TO WORKSHOPS

WORKSHOP TOPIC 1 - FACULTY AND STAFF

(Section 2 of "Tentative Guidelines")

This workshop will attempt to recommend the types of faculty, by discipline, which should be available to the overall program--including basic science and applied (clinical) areas.

Qualifications of various types of clinical faculty should be recommended. This includes academic preparation, clinical skills, discipline or emphasis area, and professional maturity considerations.

Types and qualifications of faculty-practitioner-educators from other health science disciplines should be recommended.

To what extent is it desirable that the clinical faculty person be practicing in patient care-related functions in order that the practitioner educator concept be maintained?

Other recommendations deemed appropriate to the subject may be added at discretion of the workshop leader and participants.

WORKSHOP TOPIC 2 - THE SERVICE ROLES OR FUNCTIONS

(Section 3 of "Tentative Guidelines")

This workshop is intended to establish recommendations concerning those service functions and/or teaching models which must be present in order to adequately support a Pharm.D. program.

This workshop is not intended to recommend how much, if any, time a student should be involved in each service function--this will be done by Workshop 5.

Maturity and utilization factors should be considered. For example, mere presence of a Drug Information Center may not be sufficient if it is not utilized by health professionals with any frequency.

Services, professional functions and facilities might be prioritized according to those which must be present if a Pharm.D. program is offered, those which would be desirable and those needed only if specialty training is provided.

Physical and financial resources needed to provide, conduct or otherwise support these functions might be given consideration.

Other recommendations deemed appropriate to the subject may be added at the discretion of the workshop leader and participants.

WORKSHOP TOPIC 3 - CURRICULUM

(Section 4 of "Tentative Guidelines")

Develop a series of statements which describe--in a general way-- those competencies which a Pharm.D. graduate should possess, irregardless of program emphasis. These should lead toward helping distinguish doctoral from baccalevel programs. Accomplish this with no more than ten statements. The intent is to attempt to generally describe a "professionally more mature" graduate.

This might be approached by asking the question, "Should you have the Pharm.D. degree if you cannot do this?"

Other recommendations deemed appropriate to the subject may be added at discretion of the workshop leader and participants.

The committee considered at length the degree or depth to which the conference should go in developing competency statements. Because of the complexity and overall large scope of such a project, it was decided that we should look for the "cardinal features" which make the Pharm.D. clearly different. These might be competencies not expected of the B.S., or they might relate to degree of sophistication of performance. The ones recommended should be those which must be present in every doctoral program.

WORKSHOP TOPIC 4 - BASIC SCIENCES AND PRE-CLINICAL CURRICULUM

(Section 4 of "Tentative Guidelines")

Page 6 of the "Tentative Guidelines" states, "Standards reguire demonstration of 'a professionally oriented curriculum with biomedical and clinical experience significantly beyond that provided in the baccalaureate program.'"

This workshop would develop a description of a basic curriculum format which is required to establish the basic science and pre-clinical component of the Pharm.D. program.

Types of courses (by discipline), approximate time devoted to each, levels of sophistication to be achieved should be stated. Qualitative and quantitative differences from baccalaureate-level courses should be identified where possible.

Which basic science courses are a "must" and which are "desirable"?

Other recommendations deemed appropriate to the subject may be added at discretion of the workshop leader and participants.

WORKSHOP TOPIC 5 - THE CLINICAL CURRICULUM

(Section 4 of "Tentative Guidelines")

Page 7 of the "Tentative Guidelines" states, "The quantity and quality of the clinical experience component of the program are two of the benchmarks of differential practice competencies between the two professional curricula."

This workshop would recommend those specific types of clinical experiences which should be common to all programs. This should include a recommendation of time devoted to the various components of the clinical experience. Recommendations should be developed for the amount and types of elective experiences which should be available. Appropriate student experiences, including the degrees of responsibility for decision making, should be recommended for each component of the core component of the clinical experience. This is of importance to development of the "professionally more mature" graduate.

The nature and degree of interdisciplinary involvement should be considered.

Courses directly supportive of the clinical component should be recommended.

The guidelines recommend 1500 hours as the minimum clinical experience. Can the nature of this be defined more precisely? What fraction should be closely supervised by a clinical pharmacist preceptor versus independent study? What degree of continuity of involvement should there be in the 1500 hours?

The relationship between the clinical component of the Pharm.D. curriculum and residencies needs to be brought into focus, perhaps as a part of consideration of the 1500 hour guideline.

Workshop Topic 5 - THE CLINICAL CURRICULUM was subdivided into three topics to be addressed by Workshop Groups at the Conference. The bound discussion papers for Topic 5 served as resource material for Conference Groups 5-A/B, 5-C/D, and 5-E. The additional charges to these Workshop Groups are listed below.

Assignment - Conference Groups 5-A and 5-B:

THE CLINICAL EXPERIENCE COMPONENT

The "Tentative Guidelines" recommend 1500 hours as the minimum clinical experience. What are the fundamental types of clinical experiences which are required for quality doctoral education and which should comprise a part of the 1500 hour requirement? What should be the relative amounts of time devoted to the various types of required experiences? Recommendations should be developed for the approximate amount and types of elective experiences which should be made available. What should be the amount and nature of interdisciplinary involvement in these clinical experiences?

What activities and level of skills must be developed during these clinical experience programs to make the doctoral graduate unique compared to his/her baccalaureate degree counterpart?

Other recommendations deemed appropriate to the subject may be added at the discretion of the workshop leader and participants.

Assignment - Conference Groups 5-C and 5-D:

STUDENT RESPONSIBILITIES

On Page 8, the "Tentative Guidelines" state that "ample opportunity for professional decision making and the acquisition of clinical judgment skills sshould be provided so as to insure compliance with the standard that the 'program will develop students professionally more mature than those in the baccalaureate programs.'"

What are the "hallmarks" of the professionally more mature graduate? What is the appropriate degree of responsibility for decision making during clinical experience programs? How much personal responsibility for patient care should be assigned to the student? What is the appropriate degree of supervision which should be given the doctoral student?

The relationship between the 1500 hour clinical component of the Pharm.D. curriculum and residencies needs to brought into focus. What should be the purpose of the predoctoral experience as compared to the residency?

Other recommendations deemed appropriate to the subject may be added at the discretion of the workshop leader and participants.

Assignment - Conference Group 5-E:

OUTPATIENT AND AMBULATORY CARE

Page 7, lines 11-17 of the "Tentative Guidelines" states, "although both a clinical clerkship and externship are required in each curricula, the major experiential emphasis of the doctoral program should be in patient care areas of hospitals and related clinical facilities. Externship experience in outpatient areas should comprise the minority of experience and should involve closure or logitudinal experience, as well as research in ambulatory patient care."

This workshop should develop recommendations for the types of outpatient care activities with which the doctoral candidate should be made familiar. Should the "guidelines" place more emphasis on ambulatory outpatient care? If so, what are the minimal abilities which should be developed and experiences which should be developed and experiences which should be provided?

Other recommendations deemed appropriate to the subject may be added at the discretion of the workshop leader and participants.

WORKSHOP TOPIC 6 - EVALUATION AND STUDENT QUALIFICATION

(Sections 5 and 6 of "Tentative Guidelines")

What should be evaluated and what types of evaluative mechanisms should be employed?

Recommendations of criteria for accepting students into Pharm.D. programs, must consider both post-baccalaureate and pre-baccalaureate entry levels.

WORKSHOP TOPIC 7

Conference Group 7 was assigned to work on a topic added in the final stages of the conference planning. There were no discussion papers for Topic 7. The assignment is described below.

Assignment - Conference Group 7:

> Page 7, lines 5-6, of the "Tentative Guidelines" states, "Disease states and therapeutics must be studied from a holistic view including social, behavioral, and anthropological implications." What would be appropriate indicators that this occurs in the Pharm.D. curriculum? What types of courses might be needed? What experiential programs should be available?
>
> Other recommendations deemed appropriate to the subject may be added at the discretion of the workshop leader and participants.

APPENDIX III

POSITION PAPERS ON WORKSHOP TOPICS

The following papers were prepared at the request of the Conference Steering Committee. They were mailed to all conference participants 10 days in advance of the Conference. The material contained in these papers represents the personal opinions of the authors, intended to serve as "discussion stimulators" during the Conference.

WORKSHOP TOPIC 1 - FACULTY AND STAFF
POSITION STATEMENT

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Faculty

The teaching faculty in the Doctor of Pharmacy program should be composed, at minimum, of faculty from the following disciplines:

Clinical Pharmacy
Biopharmaceutics and Pharmacokinetics
Pathology
Clinical Biochemistry
Pathophysiology and Medicine
Clinical Pharmacology
Biostatistics, Drug Literature, and
Drug Information Services

Other desirable discipline areas would include public health, health care administration, institutional pharmacy practice, management sciences, and psychosocial aspects of drug use. The above disciplines are not intended to by mutually exclusive as one faculty member may provide expertise in more than one discipline and teach in the corresponding areas of the curriculum (e.g., pathology and clinical biochemistry). However, this should clearly be the exception rather than the rule. While the faculty member(s) in many of these disciplines might not necessarily hold their academic appointment within the College of Pharmacy, their involvement should be of actively teaching in the program and not merely being available as consultants or resource persons for other faculty members teaching corresponding areas in the curriculum.

The clinical pharmacy faculty should represent the largest single group of the faculty teaching in the Doctor of Pharmacy program and a majority of these should typify the clinical practitioner-educator-scholar model. This recognizes that, at any given point in time, not <u>all</u> clinical faculty will be simultaneously involved in patient care, education, research, and program administration. However, over time, each should be involved in all of the preceeding (program administration is intended to include student advisement, college committee participation, curriculum and course planning, etc.) The organization and administration of the program should be such that the concept of a faculty as a self-governing body is mirrored in the clinical faculty particularly with reference to the determination of curriculum and standards.

Clinical Faculty

Clinical faculty should possess advanced education to the professional doctoral or masters level including advanced academic preparation and clinical education and training. Additionally, at least some members of the faculty should be experienced in clinical and professional practice research (not

necessarily any one individual in both). This is not intended to specifically exclude faculty with baccalaureate education with significant credentials of experience and expertise who may make a valuable contribution to the education program.

Recognizing that experience criteria (set number of years) can be arbitrary, a major portion or majority of the clinical faculty should possess additional experience at least equivalent in length to their formal clinical education (i.e., three years). (The faculty, when the student starts, should have at least as much experience as the student will have when the program is completed.) Moreover, the use of residents as the primary clinical faculty for students in the preceeding year is neither anticipated nor condoned.

Discipline or emphasis representation of the clinical faculty should include, as a minimum, internal medicine, surgery, pediatrics, psychiatry and should derive from experience or current practice locus rather than narrowness of the faculty member(s) formal academic and clinical preparation.

A clinical faculty to Pharm.D. ratio of 3-4:1 is recommended. If the same group of faculty also have significant teaching responsibility in the clinical component of the baccalaureate program a lower ratio is anticipated. Such a ratio takes into consideration extrapolations which can be made from the relationship among the number of clinical faculty; the number of "typical 18-30 bed" services on which a practitioner-education role model can reasonably be provided; therefore, the number of role-model relevant patients available for teaching; and the number of students that can be accommodated on an active service in a teaching hospital.

Clinical skills demonstrated by the faculty should include, as a minimum, demonstrated competence in:

A. interpretation, analysis, and collation of clinical data

B. application of drug knowledge to patient care

C. ability to work effectively with patients and other health professionals

D. ability to organize and supervise provision of pharmaceutical services and/or integration of the clinical aspects of drug use with more traditional pharmaceutical services

Such skills should consistently be applied in an ongoing, continuous patient-care role. The practitioner-educator model is viewed as essential to optimal education and training of the student clinician and should be embodied in the majority of the clinical faculty.

Faculty From Other Health Science Disciplines

Faculty from other health science disciplines with didactic or clinical teaching responsibilities in the Doctor of Pharmacy program should meet one of the following criteria:

A. hold an appointment in that discipline's academic unit and thus, have the appropriate credentials and competence to have received and continue with such an appointment. The suitability of the individual to teaching in the Doctor of Pharmacy curriculum should be the province of the college faculty, however, rather than an assignment made by the respective unit.

B. have qualifications such that the individual would normally be considered eligible for an appointment in an academic unit of that discipline. Whether the individual holds a regular or adjunct faculty appointment or teaches in the program without formal appointment, there should be evidence that such qualifications have been reviewed by the appropriate College of Pharmacy committee with the assistance of appropriate outside opinion (e.g., the corresponding academic unit at a non-affiliated university).

FACULTY FOR PHARM.D.

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1. Set Objectives - The qualifications of a faculty for a Pharm.D. program will vary with the objective of its teachers. What do they want to train the Pharm.D. candidate to do? If their aim is to prepare students principally to dispense prescriptions written by health care practitioners and to do this about 90 percent of their time, it should be obvious that the type of instructions required will be vastly different than if other objectives are sought.

If, on the other hand, the aim is to prepare pharmacists who can function effectively as applied clinical pharmacologists working in an interdisciplinary health care setting in close association with physicians and other health professionals serving the health needs of patients, then an entirely different type of faculty is required.

2. Decide Who Will Dispense Prescriptions - If the first objective is sought, the five- or six-year program is far too costly for society and prepares the individual at a level far beyond that for which he will be called to function. A pharmacy technician or technologist could be trained to dispense prescriptions.

3. Faculty Required For Pharm.D.:

Clinical Faculty - Assuming the objective is to prepare the Pharm.D. as an applied clinical pharmacologist - which I have discussed elsewhere (Journal of Clinical Pharmacology 12:384-392 (Oct.) 1972) - I believe that the clinical faculty role model should possess these attributes:

A. S(he) should be especially strong in knowledge of biopharmaceutics and pharmacokinetics and their application to the sick patient. Instruction should include laboratory work.

B. S(he) should have a good knowledge of pharmacology and therapeutics in order to facilitate communication with other health professionals and to better serve the patient.

C. S(he) should have an understanding of the thought processes through which the physician arrives at his diagnosis and of the processes whereby specific drugs are selected for the treatment of patients with particular clinical conditions.

D. S(he) should have a graduate level course in biostatistics and a strong course in pathophysiology.

E. S(he) should have a good background in the socio-psychological aspects of disease and of health care.

F. S(he) should be able to read, understand, interpret and discuss the patient's medical record.

G. S(he) should be experienced in counseling patients, physicians and other health personnel on the safe and appropriate use of drugs.

H. S(he) should have experience in gathering, analyzing, interpreting and disseminating a wide variety of drug information from various recognized sources.

I. S(he) should have served either an ASHP residency, as a Teaching Fellow, or have had equivalent clinical experience.

J. S(he) should be a practicing clinical pharmacist with daily responsibility for the care of patients. (See "Models for Professional Practitioners," Drug Intell. Clin. Phar. 7:201 (May) 1973 and "Establishing a Model for Clinical Practitioners," Ibid. 251 (June) 1973.

A clinical pharmacy faculty with these ten attributes would be excellent teachers of clinical pharmacy and creditable role models for students.

Basic Science Faculty - In the disciplines of pharmaceutics and pharmacology, there is potentially a great direct relationship between them and pharmacy practice. However, these must be nurtured by faculty involvement in tasks which will directly benefit patients, as for example, work in a pharmacokinetic laboratory or solving a problem related to the choice and dosage of a drug for a given patient. In some instances, departments of pharmacy administration can enrich the students' background in socio-psychological aspects of health care, although many such departments seem to be more economically than socially oriented.

In essence, the more the basic science teacher knows and understands the application of the subject he teaches to the welfare of the patient, the more "clinically oriented" his courses will become.

WORKSHOP TOPIC 2 - THE SERVICE ROLES OR FUNCTIONS
POSITION STATEMENT

PHARMACY ROLE MODELS AND SERVICES NECESSARY TO SUPPORT A QUALITY PHARM.D. PROGRAM

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Pharm.D. programs should train practitioners capable of providing the highest level of pharmacy services. The majority of graduates, after appropriate residency training, should be providing direct clinical pharmacy services, often in a specialty area. Others may be functioning in drug information centers or clinical pharmacokinetic laboratories. Some should become directors of pharmacy services and hasten the evolution of pharmacy departments structured on sound management and clinical and scientific principles of practice. For Pharm.D. programs to be successful in training the highest level of pharmacy practitioners, several pharmacy services and practice role models are required in the school of pharmacy's programs.

A medical school faculty is expected to provide the highest level of medical care, in addition to teaching and conducting relevant research. The same must be the case for the faculty of Pharm.D. programs. Unless excellent comprehensive pharmacy services are encountered by the student, his future performance is likely to fall short of expectations due to a lack of quality experience and exemplary role models. A hospital in which poor control of drug quality is allowed, inadequate sterile product facilities and programs exist, poor drug distribution systems continue and marginal pharmacists practice is not the place to train any level of pharmacy students, especially the Pharm.D. student. A few clinical faculty attending rounds in a hospital is not an adequate foundation for Pharm.D. education.

In addition to a high level of drug quality control and drug use control in the teaching facilities, comprehensive clinical pharmacy services must be provided. Many of the pharmacy faculty should be practicing clinically. They should be providing intensive drug therapy monitoring and consultation services as part of the total services of the pharmacy department. These services should be continuous and not subject to decadence at exam and vacation time. In this practice arena, the Pharm.D. faculty should also teach and conduct research.

For pharmacy services to be of the highest quality in teaching hospitals and clinics, several clinical pharmacy specialists are required on the faculty. Several general clinical pharmacists practicing on inpatient medical teaching wards are necessary. These faculty should be knowledgeable in the applied pharmaceutical sciences, internal medicine and clinical pharmacology. At least one faculty should be a pediatric clinical pharmacist. Pediatrics constitutes an important area of medical practice, and pediatric drug therapy is sufficiently diverse to require a clinical pharmacy specialist for practice and teaching excellence. A psychiatric clinical pharmacist is likewise a required faculty

component for practice and teaching excellence to occur in the psychiatric setting. Psychiatric patients are clustered in mental hospitals, community health centers and university teaching hospitals. One or all of these facilities should be available as a service and teaching resource.

Every Pharm.D. program should have an ambulatory care teaching and practice component. At least one ambulatory care clinical pharmacist should be on every faculty. This faculty member may be providing clinical pharmacy services in a primary health care setting, group family practice or hospital clinics. The faculty should be intimately involved with patient education, therapeutic monitoring and assurance of rational drug therapy. The mere operation of an outpatient dispensary is insufficient as a teaching and practice model. Other faculty members needed are the critical care clinical pharmacist and the clinical toxicologist. Perhaps these members are not an absolute requirement at this time, but they are recommended.

As a backup for the clinical pharmacy faculty, at least one drug information specialist is required. A comprehensive drug information center is fundamental to the teaching and practice programs. This center should be used by the medical and pharmacy communities. Another required faculty resource is the clinical pharmacokineticist who provides patient services and research support. A kinetics laboratory in the patient care environment is required for this faculty member to be functional. Assays for digoxin, gentamicin, theophylline and other appropriate drugs should be routinely available.

In order for there to be leadership and cohesiveness to the service program, at least one faculty member should serve as director of pharmacy services. This director should correspond in importance to the chief of medicine, for example, in the medical school. This faculty member must insure that total services are of the highest quality, that they are integrated in an efficient and continuous fashion and that service, teaching and research are synchronous.

TABLE 1

ROLE MODELS NECESSARY IN PHARM.D. PROGRAMS

Role Model	Required	Recommended
1. General Clinical Pharmacist	✓	—
2. Pediatric Clinical Pharmacist	✓	—
3. Psychiatric Clinical Pharmacist	✓	—
4. Ambulatory Clinical Pharmacist*	✓	—
5. Critical Care Clinical Pharmacist	—	✓
6. Clinical Toxicologist	—	✓
7. Clinical Pharmacokineticist	✓	—
8. Drug Information Specialist	✓	—
9. Director of Pharmacy Services	✓	—

* May be one or more of the following locations: group family practice, hospital outpatient clinics, primary care setting.

TABLE 2

FACILITIES NECESSARY FOR PHARM.D. PROGRAMS

	Facility	Activity	Required	Recommended
1.	Drug Information Center	Services to clinical faculty, medical center staff and local medical and pharmacy personnel	✓	—
2.	Clinical Pharmacokinetics Lab	Direct patient assay services plus research support	✓	—
3.	Teaching Hospital Pharmacy Departments (Inpatient)	Intravenous admixtures, sterile product formulation (i.e., hyperalimentation), unit dose drug distribution system, broad range of clinical pharmacy services, drug quality control services	✓	—
4.	Ambulatory Care Pharmacy	Therapeutic monitoring and counseling, patient education, dispensing, management of chronic drug therapy, assurance of patient compliance	✓	—
5.	Pediatric Inpatient Facility	Pediatric clinical pharmacy services	✓	—
6.	Psychiatric Inpatient Facility	Psychiatric clinical pharmacy services	✓	—
7.	Medical Inpatient Facility	General clinical pharmacy services to medical patients	✓	—
8.	Intensive Care, Cardiac Care and Respiratory Care Units	Critical care clinical pharmacy services	✓	—
9.	Emergency Room	Clinical toxicology services	—	✓
10.	Radiopharmacy Lab	Preparation of radiopharmaceutical doses and compounds	—	✓

WORKSHOP TOPIC 2 - THE SERVICE ROLES OR FUNCTIONS
POSITION STATEMENT

The Service Roles or Functions Utilized for Clinical Pharmacy Education and Training

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Reference: "Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy" prepared by the ACPE - see section 3, entitled: "Physical and Financial Resources" (copy attached)

A general criticism is that the Guidelines covering this section lack any precise guidance for development and implementation of the standards. The language used is broad and even vague, so that a school/college of pharmacy would find it difficult to determine the priorities for different components of its clinical program development, where they could best be developed and utilized, the level of practice needed, the extent of their utilization, relationships, etc. The wording would suggest that most any group of clinical teaching facilities under any arrangement would be sufficient to produce a quality program.

On the other hand, there is a strong insistence (in the last two sentences of the first paragraph) that clinical instruction be provided within the context of pharmaceutical services and that "pharmacy service departments should be conceptualized as clinical departments." This, I find constraining or limiting (in terms of developing new role models within clinical care areas) and is not realistic from the way pharmacy departments are viewed by clinicians, i.e., they are not personally and directly involved with patient care on a full-time basis. In many cases the role model for clinical pharmacists does not include any drug distribution functions whatsoever, and in some instances the clinical pharmacists have service appointments in the department of medicine rather than pharmacy. I can see no good reason to exclude this arrangement if it proves workable.

A final comment I would make is that implicit in the statement (see paragraph two) that the college not disadvantage its baccalaureate program in developing a Pharm.D. program, is the idea that clinical instruction should be developed first in the baccalaureate program. My feeling is that quality programs of clinical instruction could only rarely be developed in the earlier years without a clinical faculty of sufficient strength and clinical teaching facilities/role models of sufficient experience as what one would find provided for a Pharm.D. program. And therefore, I would expect the best clinical instruction to be developed in those schools/colleges of pharmacy which either have or are in the process of developing a Pharm.D. program. It is at this level that clinical teaching innovations can be tried and where the feasibility of clinical instruction in the earlier years can be determined. Much of what had formerly been taught only to Pharm.D. students is now being offered to baccalaureate students, i.e., there is a "pushing down" effect in the curriculum.

To help gear the thinking of the workshop group to "standards and guidelines" which might more specifically meet the needs of clinical instruction at the Pharm.D. level, I am providing (attached) a working outline of functional service and teaching models needed as I see them.

Statement taken from - "Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy" prepared by the ACPE, dated June 16, 1975.

3. Physical and Financial Resources

"The resources indicated in the standards are particularly important in the effectuation of a doctoral program. The Council does not stipulate or encourage a specific type of physical facility arrangement and recognizes that variations in the curriculum often dictate dissimilar facility configurations. However, clinical facilities assume a particular significance for the doctoral program. Clinical facilities should demonstrate comprehensive pharmaceutical services of an exemplary nature. Pharmaceutical services in patient care areas should be integrated with the educational program, thereby providing role model opportunities. Pharmacy service departments should be conceptualized as clinical departments with practice and educational functions.

Physical and financial resources should not be employed for the doctoral program to the disadvantage of the baccalaureate program. If evidence to this effect develops, the Council will accordingly recommend that the college tilt its priorities toward attainment of a quality entry degree program. Standards further indicate that resources include an adequate operational budget, facilities suitable for both inpatient and outpatient educational experiences and supportive services. Clinical facilities for experimental practice outreach opportunities such as in centers for primary care and areas deficient in health services should be available."

Initial Premise - A distinction is made throughout this paper as to what facilities and functional role models are needed for clinical education and training at the a) baccalaureate, b) doctor of pharmacy, c) post-doctoral residency levels. The premise is made here that performance objectives and expectations for practice are aligned with these different levels as follows:

a) B.S. in Pharmacy - general practice of pharmacy with ability to broadly apply drug knowledge to the treatment and care of patients (particularly chronic, long-term care).

b) Pharm.D. - practice of clinical pharmacy within the patient treatment and care setting with ability to advise on all aspects of drug therapy for individual patients - serving as an integral member of an organized patient care team.

c) Post-Doctoral Residency Training - in addition to the above, has specialty training and advanced ability in a particular area of therapeutics and associated clinical care.

The outline below enumerates those functional service and teaching models considered important in providing clinical pharmacy education and training. These are listed in the order of their logical development, outlining first the more central, supportive functional models, followed by those functional models to be developed within the clinical care settings. A priority has been assigned to each of these (for both B.S. and Pharm.D. programs) according to education and experience needs, where: 1 is essential; 2 is highly desirable; and 3 is considered desirable.

Functional Service/Teaching Model	Priority	Accommodation*
I SUPPORTIVE		
A. Medical library with on-line automated literature search and retrieval capabilities.	2-B.S. 1-Pharm.D.	10-20 students
B. Drug information center	1-B.S. 1-Pharm.D.	5 + students
C. Biopharmacokinetics laboratory	2-B.S. 1-Pharm.D.	4 + students
D. Clinical pathology laboratory	3-B.S. 1-Pharm.D.	6 + students
E. Toxicology laboratory	3-B.S. 2-Pharm.D.	6 + students
F. Radiopharmaceutical laboratory	3-B.S. 2-Pharm.D.	6 + students

*"Accommodation" here refers to the number of students who can be provided supervised instruction or training at any one time.

Functional Service/Teaching Model	Priority	Accommodation*
II PATIENT CARE		
A. Prescription service centers wherein patient-medications are monitored and patients are consulted (community pharmacies and/or outpatient hospital pharmacy services).	1-B.S. 2-Pharm.D.	2 + students per center or pharmacy
B. Neighborhood health care centers, public and/or private (clinics)	1-B.S. 1-Pharm.D. 2-Residency	3 + students per center or clinic
C. Hospital care: acute, short-term		
1. general medicine units (20 + beds each) and associated clinics	1-B.S. 1-Pharm.D. 1-Residency	3-4 students per unit
2. general surgery units (20 + beds each) and associated clinics	2-B.S. 1-Pharm.D. 1-Residency	3-4 students per unit
3. OB-GYN units (20 + beds each) and associated clinics	2-B.S. 1-Pharm.D. 2-Residency	3-4 students per unit
4. Pediatric units (20 + beds each) and associated clinics	2-B.S. 1-Pharm.D. 1- Residency	3-4 students per unit
5. Psychiatric units (20 + beds each) and associated clinics	2-B.S. 1-Pharm.D. 1- Residency	3-4 students per unit
6. Emergency treatment and care center	3-B.S. 1-Pharm.D. 1-Residency	2 + students
D. Hospital care: chronic, long-term - nursing home and/or skilled nursing facility	1-B.S. 1-Pharm.D. 2-Residency	3 + students per home or facility

Elaboration (on the above)

I-A. Medical Library
- close proximity (walking distance) to areas of clinical training
- may include pharmaceutical literature or supplement that housed elsewhere, e.g., within the school/college of pharmacy

I-A. Medical Library (continued)
- has on-line, automated literature search and retrieval capabilities
- has a full-time, trained medical librarian
- has a member of its staff who can train pharmacy students in library systems and search strategies

I-B. Drug Information Center
- close proximity (walking distance) to areas of clinical training
- should include in its holdings primary and secondary drug literature, i.e., specialized drug information services tailored to the clinical pharmacist's needs, e.g., commercially packaged index card systems, abstracts, microfische, tapes, drug monographs, etc.
- emphasis should be given to methodologies for evaluating the quality of published drug information
- the service function should be directed primarily to the needs of practicing health professionals in need of therapeutic drug information
- the center should be headed full-time by a faculty member specially trained in the area of drug information service

I-C. Biopharmacokinetics Laboratory
- close proximity (walking distance) to areas of clinical care and training
- include instrumentation sufficient to conduct assays and determine blood levels of several drugs commonly employed in patient care, particularly those used in treating cardiovascular disease
- there should be an identifiable and continuous service function operating between this laboratory and the patient care areas
- the laboratory should be headed full-time by a faculty member specially trained in biopharmacokinetics

I-D. Clinical Pathology Laboratory
- within the area of clinical training, should include capabilities for routine blood chemistry work and analysis of biopsy material

I-E. Toxicology Laboratory
- close proximity (walking distance) to areas of clinical training
- adequate equipment and staff to conduct toxicology screens of blood specimens and other biological material
- headed by a full-time, specially trained faculty member or other individual available for student instruction

I-F. Radiopharmaceutical Laboratory
- close proximity (walking distance) to areas of clinical training
- provides the usual service functions assigned to such a laboratory
- headed by a full-time, specially trained faculty member or other individual available for student instruction

II-A. Prescription Service Centers
- serving ambulatory patients (private or public care)
- patient-medication profile records are maintained for all patients
- patient consultation regarding the prescribed medication(s) and their use during home care is an acknowledged function of the pharmacist

II-A. Prescription Service Centers (continued)
- there are active and continuous communications between the pharmacist and the prescribing physicians (in the area)
- semi-private areas are set aside for patient consultation and monitoring certain physical signs and symptoms of drug effects in the patient

II-B. Neighborhood Health Care Center/Clinic
- may be public or privately operated
- provides some primary care functions as well as continuous screening and monitoring of medical problems
- includes an acknowledged role of the pharmacist in monitoring drug therapy through patient interviews

II-C. Hospital Care: Acute, Short-Term

The various clinical areas outlined in this section are considered essential for clinical training at the Pharm.D. level. The comments which follow are applicable to any one of these areas and serve to characterize the faculty role model necessary for student participation.

- at least one pharmacy faculty member, clinically trained, is required full-time on each of the patient care units described
- the pharmacy faculty member is viewed as a practitioner-educator and thus, has a direct responsibility for patient care service as well as student instruction within the same setting. Accordingly, his/her position may be jointly supported (funded) by the patient care institution.
- the pharmacy faculty member is viewed as an integral member of the patient care team, sharing responsibility with the physician for the safe and effective use of drugs in patients on a continuous basis. There should be clear evidence of this shared responsibility through participation in work rounds, chart entries or separate notations, and conferences with attending physicians, nurses and other team members.
- instruction in the rational use of drugs may be extended to include students of nursing and medicine. Accordingly, his/her position may also be supported, in part, by another department or school/college, e.g., nursing or medicine.
- there must be a system established to assess student learning, i.e., the mastery of certain specified facts, skills and concepts to be applied to clinical pharmacy practice.

II-D. Hospital Care: Chronic, Long-Term
- may include nursing homes or skilled nursing facilities (other comments are the same as for II-C)

Other Considerations

Student Involvement in Patient Care

Students receiving instruction in patient care areas should be allowed to involve themselves with service functions, under the direct supervision of a faculty member. The learning experience should progressively develop

from one of observation, show-and-tell, to direct participation at more advanced levels of training. In clinical situations, it is important that the student develop some ability to solve problems independently and then defend his/her judgement before his/her peers as case presentations. Thus, the necessity for students to see patients, attend rounding sessions, review charts and progress notes, and to periodically utilize conference rooms in adjoining areas are also important considerations for an effective clinical teaching program.

Affiliation Agreements and Contracts

With each and every "off-campus" clinical training site, there should be a teaching affiliation agreement in effect between the pharmacy school/college and the facility/institution where clinical training is to take place. Such agreements should be considered contracts with specific terms given for the kind and extent of resources to be utilized, what privileges are allowed for students with regard to facilities and patients, insurance coverage, and method and amount of reimbursement if there is to be any. The individual(s) responsible for instruction and supervision of students within the facility or institution should be named.

WORKSHOP TOPIC 3 - CURRICULUM
POSITION STATEMENT

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In an attempt to identify those special skills which should be posessed by a pharmacist trained at the Pharm.D. level, and which exceed those of the B.S. pharmacist, it might be useful to make a statement about the competencies expected of the pharmacist at the B.S. level, for the sake of comparison.

The B.S. Pharmacist as a Medication Management Specialist

In addition to the traditional pharmacy functions (purchasing, storage, dispensing), the B.S. pharmacist should be competent to provide patient counseling relative to the safe and appropriate use of drugs (prescribed and OTC); he should maintain a patient medication record as a basic practice tool, and should discuss freely and intelligently any patient medication problems with the patient's physician. He should be competent to screen for allergies, clinically significant drug interactions, pharmacologic duplications, adverse drug reactions, and poor patient compliance. Although not widely recognized as a traditional component of pharmacy practice at the B.S. level, the monitoring of response to certain drugs in chronic diseases, via vital sighns, urine chemistry, etc., should be encouraged. It is recognized that there is a significant opportunity for the B.S. pharmacist to practice good clinical pharmacy, and he should be encouraged to develop a special patient-pharmacist relationship, especially in community practice.

The B.S. pharmacist should be motivated to insure his continued competence through a systematic approach to continuing education.

The Pharm.D. Graduate as a "Professionally More Mature" Pharmacist

The pharmacist trained at the Pharm.D. level should possess certain additional skills, or higher level of skills, and more professional maturity than the B.S. pharmacist.

The skills which all Pharm.D. graduates should possess might be categorized as follows:

1. Direct Patient Oriented Services

   Based on a patient's unique clinical status, the pharmacist at the doctoral level should be competent to make recommendations on plans of treatment, or evaluate existing plans of treatment, taking into account the patient's unique clinical status, therapeutic goals, endpoints, and alternatives. He should be competent to monitor for response, allergy and toxicity. Additionally, he should be competent to counsel patients with unusual health problems, such as renal dialysis patients, on the safe and appropriate use of drugs.

2. Indirect Patient Oriented Services (Information and Education)

At the Pharm.D. level the pharmacist should be competent to utilize the clinical literature effectively in providing drug information. He should be competent to retrieve information effeciently, to critically evaluate the literature, and to communicate an effective response, either verbally or in writing, to the initiator of the request.

Given a group of learners (pharmacy students, nursing students, participants in in-service classes, and other health care personnel), the Pharm.D. graduate should be able to:

a. develop lesson plans, behavioral objectives, and evaluation instruments for classes to be conducted on the pharmacologic, toxicologic, therapeutic, or pharmaceutic aspects of a particular drug or groups of drugs;

b. conduct classes, at a level appropriate for the audience, on these topics above.

3. Applied Clinical Research

Given a problem to be investigated involving patients and drugs, the Pharm.D. graduate should be able to:

a. state clearly the hypothesis and objectives of the study;

b. participate in the construction of an appropriate research protocol;

c. make accurate observations and collect appropriate data;

d. evaluate and interpret the data, using appropriate biostatistical treatment of the data;

e. draw valid conclusions from the data;

f. communicate his results and conclusions to others via seminars and/or publications.

4. Product Oriented Services

The Pharm.D. graduate should demonstrate an absolute mastery of information related to drug products, including product availability, approved indications, dosage schedules, routes of metabolism and elimination, major toxic effects, storage requirements, USP dispensing information (where applicable), and special legal requirements in storage and distribution. His recall of such information should be almost encyclopedic.

The doctoral pharmacist should demonstrate special skills in applying principles of biopharmaceutics and pharmacokinetics to the solution of patient problems.

The doctoral pharmacist should be knowledgeable concerning drugs in current clinical trial, and should be familiar with the development of IND and NDA requests and with the requirements for handling investigational drugs.

5. Management Skills

The Pharm.D. graduate should demonstrate considerably greater skills in management of one or more pharmacy practice settings than the B.S. pharmacist, but not necessarily at the level of a pharmacist who has taken a residency. Practice settings include (but are not limited to) hospital pharmacy; pharmacies associated with HMO's family practice centers, and extended care facilities; pharmacy components of group practices; and community pharmacies.

Summary

The pharmacist at the professional doctoral level should possess certain competencies in the following areas: direct patient oriented services, informational and educational services, and management services. He should be capable of participating in a highly sophisticated manner in the interdisciplinary delivery of health care. He should be highly motivated to maintain competence through appropriate continuing education efforts. He should be a leader in his field.

WORKSHOP TOPIC 3 - CURRICULUM
POSITION STATEMENT

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We have a "once only" opportunity to make recommendations for the accreditation standards of the Doctor of Pharmacy (Pharm.D.) program. Let's do it logically, realistically and competently.

Differences Between the Baccalaureate and Doctoral Pharmacy Practitioner

> We can all perceive the differences between ourselves and our inferiors, but when it comes to a question of the difference between us and our superiors, we fail to appreciate merits of which we have no proper conception.
>
> James Fenimore Cooper: The American Democrat

Distinguishing between the baccalaureate and doctoral pharmacy practitioners is similar to distinguishing between B.S., M.S. and Ph.D. chemists. Although the B.S. chemist and Ph.D. chemist have the same initial background and may, at times, work on the same types of problems, there is a difference in (1) the level of specialized training and knowledge due to additional study and practice or research experiences, (2) the level and types of decision-making and problem-solving capability and (3) the degree of detail of information transmitted.

One way to determine differences is to examine current practices.

Current Roles of the B.S. and Pharm.D. Pharmacist

The baccalaureate pharmacist is trained and educated for a wide range of scientific, professional and managerial functions which best serve the needs of the community and possesses sufficient adaptability to meet the demands of a changing health care delivery system.

He is the last link in the delivery of life-saving but potentially dangerous drugs to the public. Because of his knowledge, the pharmacist helps assure safe distribution of drugs to patients. He is responsible for designing and implementing a drug distribution system that insures the right drug or drugs is (are) dispensed to the proper patient at the proper time. This distribution

function includes maintaining product quality through proper storage, and application of the rules and regulations of federal, state and local governments to assure safe and appropriate distribution of drugs and accessories. He is trained and educated to compound prescription orders to produce a product that is stable, uniform and accurate.

He often serves as the first contact into the health care system and can refer patients to appropriate medical personnel when needed or suggest non-prescription drugs for certain health problems.

Many pharmacists maintain medication records which serve as information sources about the patients' drug utilization to physicians, emergency rooms and hospitals. These records also alert the pharmacist to the patient's drug allergies and idiosyncrasies to assure that problem drugs are not dispensed to these patients. Records also help eliminate duplicate drugs from being dispensed to patients seeing more than one medical specialist.

The baccalaureate pharmacist serves as a practitioner-teacher for all aspects of contemporary community practice.

The doctoral pharmacist applies his knowledge of the patient's medical problem and his expertise on drug action to monitor and optimize drug therapy. He is able to detect drug-related problems, evaluate their clinical significance and to provide solutions to these problems. He may become involved in research to find solutions to these problems, test these solutions in the clinical setting and translate these solutions into pharmacy practice.

Since, unbiased, reliable and comprehensive information on drugs is not yet easily obtained, doctoral pharmacists are capable of evaluating and communicating current clinical information on drugs to all members of the health professions. The doctoral level pharmacist specializes in drug utilization and associated problems. Doctoral level pharmacists have the expertise to design dosage scheduling based on patients' individual parameters. These pharmacists, in association with the scientific faculty are capable of developing methodologies of determining blood levels of drugs on a routine basis to optimize drug therapy.

The doctorate pharmacist is educating students in baccalaureate pharmacy programs in the clinical aspects of pharmacy practice. He emphasizes the clinical application of scientific and pharmacetuical information into pharmacy practice as it pertains to daily patient care. He has the responsibility to help educate students to fill expanded roles.

To summarize, the baccalaureate pharmacist is primarily involved in all aspects of distribution of drugs to patients. On the other hand, the doctorate pharmacist is primarily concerned with the consequences of drug therapy in patients. He identifies drug-related problems and is involved with the physician in their prevention and management.

Goal Statements

Those who cannot remember the past are condemned to repeat it.
Santayana: Life of Reason

In developing the goal oriented statements below the following assumptions were made:

1. The doctoral level practitioner is an independent professional.

2. With the exception of California, most doctor of pharmacy graduates practice in an institutional setting. This will bias some of the statements.

3. The Doctor of Pharmacy practitioner exists to improve patient/client welfare and this practitioner can only practice within the existing health care system.

In the process of developing an educational program three questions must be answered. These are:

1. Where are you going?
2. How are you going to get there?
3. How will you know when you have arrived?

The statements below are to answer the first step, i.e., what will the graduates of the program be able to do. The individual schools should determine how to meet these goals, how students' performances will be evaluated, and how the program is to be evaluated. Accreditation standards should insure that these three questions are properly answered by each school which seeks to have its program accredited.

1. The graduate should be able to help in disease prevention and promotion of wellness. He should be able to recognize potential medical problems; have a knowledge of health care and social services available; monitor drug usage and adverse drug reactions and help develop drug surveillance reporting systems.

2. The graduate will be able to monitor drug therapy. In order to do this, he must be able to understand disease processes, determine proper drug therapy and know how it will affect the disease process; detect adverse drug reactions and drug interactions, evaluate their significance and recommend solutions to overcome them; interpret clinical laboratory data and physiological function tests and apply them to the drug therapy, and be able to evaluate quantitative relationships between pharmacological effects, drug absorption, metabolism, distribution, and excretion, and plasma and tissue levels of the active drug moiety.

3. The graduate must be proficient in the storage, retrieval, and evaluation of drug literature. He can apply drug information to drug therapy.

4. The graduate will be proficient in interpersonal communications with patients and their families and all health professionals.

5. The graduate should have knowledge of the management drug distribution systems including I.V. admixture program, hyperalimentation fluids and radiopharmaceuticals.

6. The graduate must be able to view the patient in a holistic manner. This involves understanding of the social, economic and psychological factors and legal and ethical principles that may effect drug therapy. The practitioner should be able to demonstrate empathy toward the patient and the family and the health professions.

7. The graduate must be able to establish and maintain a patient data base. This includes being able to obtain pertinent medical and drug history, and be able to interpret information in medical records.

8. The graduate should be able to help manage a poison control center.

9. The graduate will be able to assume delegated authority to manage long term drug therapy. In order to do this he must be able to perform certain physical assessments, evaluate signs and symptoms, and help develop and use drug therapy protocols. This includes the development and application of nomograms and computer programs to calculate optimal dosage regimens based on individual patient parameters.

10. The graduate should develop teaching skills to be able to effectively participate in clinical and didactic instruction. The practitioner should function as a role model in acute and ambulatory patient care.

11. The graduate should be able to conduct research and develop new methodology to improve patient care related to drug use.

WORKSHOP TOPIC 3 - CURRICULUM
POSITION STATEMENT

DESIRED COMPETENCY IN DOCTOR OF PHARMACY CURRICULA

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School of Pharmacy

In preparing this position paper on competencies which should be achieved by every graduate of a Doctor of Pharmacy curriculum, I have chosen to concentrate on the following statement found in the seventh edition of the ACPE accreditation manual in the section on standards for a Doctor of Pharmacy curiculum (emphasis added):

"A doctor of pharmacy program should prepare pharmacists who can cope with the complex problems in the delivery of comprehensive health care; who possess both the knowledge and skill that enables them to function as specialists in the clinical use of drugs and who can apply the pharmaceutical and biomedical sciences to the practical problems of drug therapy; who are motivated to participate in the interdisciplinary delivery of health care; and who can function as an easily accessible health care informant and educator."

The ACPE Tentative Guidelines for Pharm.D. programs totally fails to address the evaluation of this important curriculum standard. The Council, instead, has set forth an approach to evaluate a program relative to its own "in-bred" objectives, rather than against a national standard. This is totally unacceptable for it would foster and encourage a lack of consistent quality in Doctor of Pharmacy graduates so that neither the pharmacy profession, other health care professions, the government, nor the consumer would know what to expect of the Doctor of Pharmacy in health care delivery.

The Doctor of Pharmacy graduate should possess maximal depth in the practical aspects of basic science knowledges which relate to clinical utilization of drugs. These knowledges are most appropriately found in the areas of physiology, pathophysiology, pharmacology, medicinal chemistry, biopharmaceutics, pharmacokinetics and clinical pharmacology. A Pharm.D. curriculum should be designed to specifically provide knowledges in these sciences which are mandatory for the performance of therapeutic decision making tasks. The process by which this can be accomplished was presented at the AACP Teachers Seminar at Kiamesha Lake.

The Doctor of Pharmacy graduate should also possess maximal depth in assured comprehension of these knowledges. This assured comprehension relates to translation, interpretation, and extrapolation of knowledge. Such comprehension is often accomplished in courses labelled as "Therapeutics," "Applied Therapeutics," "Clinical Pharmacology," or even "Clinical Pharmacy." It

should be stressed that we are talking about assured comprehension, and therefore this cannot be accomplished in courses designed as a mere exposure to the clinical use of drugs. An "exposure" type of course may be adequate for the baccalaureate level, but is inappropriate at the doctoral level. The doctoral level curriculum must not only assure the comprehension of knowledge, but must also provide for maximal competence in the analysis, synthesis, evaluation, and application of knowledge. This is most often accomplished in "clerkships" or "professional experience" components of curricula; however, these experiences must be designed with specific tasks in mind. By designing experiences with specific tasks in mind, a curriculum will deal not only with knowledge and comprehension, but also with specific clinical skills.

It is my contention that the most important aspect of a clinical doctoral program is in the area of assuring the attainment of patient assessment skills. Such skills currently represent the area of greatest deficiency and inconsistency in Doctor of Pharmacy education and training. Expertise in patient assessment skills involves determining the need for therapy, the most appropriate approach to therapy, and a patient's response to therapy. Most Doctor of Pharmacy curricula provide some degree of knowledge in the area of patient assessment (e.g., lectures in pathophysiology, "clinical medicine," "disease states," or "therapeutics"), but few curricula provide intensive training in the attainment of the skills involved in patient assessment. Yet the standards state the curriculum must provide such skills. The specific skills that I believe to be necessary are discussed in depth in the "Report on Clinical Education Objectives and Competencies" presented to the AACP Section of Teachers of Clinical Instruction by the Task Force on Clinical Education and Training in Undergraduate and Advanced Degree Programs.

Basically these skills involve the establishment, maintenance, and utilization of a therapeutically relevant patient data base. This data base is obtained primarily from the patient and therefore a Doctor of Pharmacy graduate must be able to obtain historical, physical, and laboratory data directly from the patient. This does not necessarily mean that a Pharm.D. is a diagnostician, but it does mean that the Pharm.D. must be able to directly obtain data to define therapeutic problems and monitor response to therapeutic regimens. Even the "consultant" Pharm.D. must possess these skills, or the resultant "consultations" will not be optimally relevant. A data base is also obtained, in part, from the patient's medical record. This requires skills in manipulating both source-oriented and problem-oriented medical records and skills in utilizing medical terminology. Certain aspects of the data base are obtained from the laboratory, and therefore knowledge of clinical chemistry and skills in defining necessary (as opposed to superfluous) laboratory data is necessary. Finally, the data base is partially obtained via communication with other health care professionals and therefore communication skills are a vital component of a Doctor of Pharmacy curriculum.

It should be stressed that the key to a competent clinical practitioner is the ability to establish, maintain, and utilize a patient data base in therapeutic decision making and monitoring of therapeutic response. The graduate must be able to determine which aspects of the patient data base are important in defining and solving therapeutic problems.

The final aspect of the curriculum standards statement that I wish to address is "motivation" or attitudinal development of the Doctor of Pharmacy student. The Pharm.D. should expect to function as an integral part of the therapeutic decision making process. It is not merely a "desired" or "hoped for" role, it is the role, and, therefore, the graduate must readily accept direct responsibility for therapeutic decision making and action. This can only be accomplished if the curriculum displays a stepwise increase in direct responsibility in clinical decision making via close supervision and verification of task performance, followed by experiences with end-of-day audit. Any member of a health care team and any consumer seeking services from the team should be able to expect from a Pharm.D. an ability to make therapeutic decisions and to accept responsibility for these decisions.

In summary, the graduate of a Doctor of Pharmacy curriculum must possess basic science knowledge of considerable depth in subjects directly related to clinical tasks; must possess ability to synthesize this knowledge into therapeutic problem definition and therapeutic plans; must possess the necessary patient assessment skills to directly assess need for therapy, appropriateness of a therapeutic plan, and put the plan into action; and must possess attitudes that will provide motivation for application of skills. The Doctor of Pharmacy curriculum must demonstrate that these aspects of knowledge, assured comprehension, synthesis, skills, and attitudes are attained by each graduate.

WORKSHOP TOPIC 4 - BASIC SCIENCES AND PRE-CLINICAL CURRICULUM
POSITION STATEMENT

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Faculty of Pharmacy
Wayne State University

The charge to this workshop is to "develop a description of the basic curriculum format which is required to establish the basic sciences and pre-clinical component of the Pharm.D. program."

The 1972 Revised Accreditation Standards issued by the American Council on Pharmaceutical Education state that the scientific component of the baccalaureate curriculum in pharmacy includes the following studies:

I. Pre-clinical Sciences

Courses in the physical and biological sciences and mathematics which are requisite for professional instruction such as anatomy, physiology, organic chemistry, physical chemistry, biochemistry, and microbiology.

II. Pharmaceutical Sciences

Courses in pharmacognosy, pharmacology, medicinal/pharmaceutical chemistry, pharmaceutics, and pharmacy administration.

III. Biomedical Sciences

A variety of professional courses. Examples cited are pathology, pathophysiology, physical diagnosis, parasitology, epidemiology and biostatistics, and clinical pharmacology.

While it is probable that all baccalaureate curricula in pharmacy meet the course requirements identified under Pre-clinical Sciences and Pharmaceutical Sciences, it is unlikely that most programs provide all of the courses cited under Biomedical Sciences. The standards further state that Doctor of Pharmacy programs should demonstrate "a professionally-oriented curriculum enriched with biomedical knowledge and clinical experience significantly beyond that provided in the baccalaureate program." This in order to prepare pharmacists "who possess both, the knowledge and skill that enables them to function as specialists in the clinical use of drugs and who can apply pharmaceutical and biomedical sciences to the practical problems of drug therapy . .".

The citation in the Standards of enriched biomedical knowledge for Pharm.D. programs, without reference to pre-clinical and pharmaceutical sciences, suggests that these latter components as developed for baccalaureate programs are not considered in need of expansion in the Pharm.D. curriculum.

In order to assess the adequacy of the Standards and address the charge of the workshop, it is first necessary to identify the responsibilities of graduates of Pharm.D. programs and to determine the competency and mastery learning skills required of program graduates to meet these responsibilities. The reader is referred to Appendix A for a statement of responsibilities, knowledge, and skills.

Accepting the recommendations in Appendix A for purposes of discussion, knowledge components #1-6, 8, 10, and 11 require input from the pharmaceutical and biomedical sciences. Courses in these areas may be divided into those (A) included in baccalaureate programs that require reinforcement but not expansion in Pharm.D. programs, (B) generally included in baccalaureate programs that require reinforcement and expansion in Pharm.D. programs, and (C) generally not included in baccalaureate programs but required or desired for Pharm.D. programs.

A. Courses in Pharmaceutical and Biomedical Sciences Included in Baccalaureate Programs That Require Reinforcement But Not Expansion in Pharm.D. Programs.

1. Pharmacognosy
2. Medicinal/pharmaceutical chemistry
3. Pharmaceutics
   a. Physical pharmacy
4. Pharmaceutical Administration
   a. Health care economics and marketing
   b. Professional management and accounting
   c. Jurisprudence
5. Pharmacy Practice
   a. Dispensing
6. Biomedical Sciences
   a. Anatomy
   b. Public Health

B. Courses in the Pharmaceutical and Biomedical Sciences Generally Included in Baccalaureate Programs That Require Reinforcement and Expansion in Pharm.D. Programs.

1. Biomedical Sciences
   a. Biochemistry
   b. Medical Microbiology
   c. Human Physiology
   d. Pathological States and Processes
   e. Immunology
2. Clinical Medicine
   a. Therapeutics
   b. Clinical Pharmacology
3. Pharmacy Administration and/or Community Medicine
   a. Health Care Administration
   b. Social Policies in Health Care
4. Pharmaceutics
   a. Biopharmaceutics and Pharmacokinetics
5. Pharmacy Practice
   a. Pharmacy Services in Health Care Facilities

An appropriate reinforcement and expansion of course material cited under Biomedical Sciences is often achieved in the course material cited under Clinical Medicine. Comprehension of the biochemical, immunological, microbiological, pathological, and physiological aspects of disease processes is a prerequisite

to the comprehension of drug pharmacodynamics and therapeutics. The terminal behavior expected of students completing the Biomedical Sciences and Clinical Medicine sequences is to be able to provide drug information to patients and health care practitioners, monitor drug therapy, aid in diagnosing drug-related or drug-induced disorders, and assist in developing individualized therapeutic regimens.

The courses cited under Pharmacy Administration and/or Community Medicine should cover the organization, provision, and financing of health care services, with emphasis on pharmacy, in addition to treating the legislative, political, and socio-economic factors affecting health care practices, procedures, and policies.

Biopharmaceutics and pharmacokinetics should be expanded to include the application of principles to the actual use of drugs in therapy. The terminal behavior expected of students is to provide drug information on the biopharmaceutic and pharmacokinetic factors influencing the choice and effectiveness of drug therapy and to participate in developing and modifying drug dosage regimens.

The course material cited under pharmacy practice should be expanded to cover the organization, management, and evaluation of pharmaceutical service programs in hospitals, extended care facilities, health maintenance organizations, and clinics. The terminal behavior expected of students is to incorporate sound management principles in developing, implementing, and evaluating departmental policies and objectives.

C. Courses in the Pharmaceutical and Biomedical Sciences Generally Not Included in Baccalaureate Programs That are Required or Desirable in Pharm.D. Programs.

1. Biomedical Sciences
   a. Clinical Pathology
2. Social Sciences
   a. Psycho-social Determinants of Disease
3. Pharmacy Administration and/or Community Medicine
   a. Biostatistics
   b. Research Design
4. Directed Research

A course in clinical pathology should cover the objectives, techniques, and significance of clinical laboratory tests, values, and procedures used in the diagnosis and treatment of disease. Some programs may prefer to incorporate these concepts within the therapeutics and clerkship sequences. The terminal behavior expected of students is to utilize the principles of clinical laboratory medicine in monitoring drug therapy and to provide information on drug-laboratory test interactions.

Coverage of the psycho-social determinants of disease should include the psychological factors and sociological patterns influencing the epidemiology of and response to disease.

Courses in biostatistics and research design should (a) familiarize students with the basic concepts and methods used in statistical analyses

and inference procedures, (b) assist students in evaluating clinical research reported in the literature, and (c) provide students with insight into the basic planning considerations required for developing, implementing, and evaluating studies. The terminal behavior expected of students is to apply statistical principles in evaluating clinical research and to participate with confidence in research projects.

Pharm.D. students should undertake an independent research project, supervised by a research committee, in order to develop skills useful in problem identification, research design, data collection, evaluation, and resolution. The terminal behavior expected of students is to apply the scientific method in problem solving and research participation.

The nature of the charge to this workshop has resulted in developing an arbitrary and seemingly inflexible structure for achieving the pre-clinical component of the Pharm.D. curriculum. The use of alternative methods and sequences to achieve similar, or perhaps more ambitious, objectives is readily acknowledged. To complete this presentation, one example of the incorporation of some of these ideas within a graduate-professional doctoral program, requiring completion of the baccalaureate in pharmacy prior to admission, is provided in Appendix B.

The Pharm.D. Program at Wayne State University, which is a graduate-professional program, has been developed to provide graduates with the education and skills to participate in health care as follows:

1. Monitor the drug therapy of patients for appropriateness and effectiveness of treatment, potential adverse drug reactions, potential compromise of therapy resulting from drug-drug, drug-food and drug-laboratory test interactions, and the stability and availability of the dosage forms selected.

2. Provide drug and drug product information and evaluation to physicians, nurses, and other health care practitioners as well as participate in conducting audits of the effectiveness of drug therapy in order to provide drugs that are safe, effective, and as economical as possible.

3. Maintain patient medication profiles of prescribed and non-prescription drugs as a reference information base, by obtaining patient drug histories where appropriate, to be used in conjunction with the patient data base collected by physicians and other health care practitioners.

4. Increase the effectiveness of drug regimens prescribed by physicians and other primary care practitioners by providing guidance and education to patients and to other health professionals on the proper use of prescription and non-prescription drugs, their side effects, contraindications, and storage conditions while emphasizing the need for compliance with the drug regimen.

5. Extend the capabilities of physicians in appropriate treatment centers by providing maintenance drug therapy and patient assessment for chronically ill patients by using pre-established treatment protocols developed by physicians in conjunction with pharmacists.

In order to meet these role objectives, we have identified 12 components contributing to competency and mastery learning skills that should be achieved by Program graduates:

1. A thorough understanding of the basic biological and physical sciences required for the baccalaureate in pharmacy such as anatomy, physiology, biochemistry, pharmaceutical/medicinal chemistry, microbiology, and physical pharmacy.

2. An intensive exposure to pharmacotherapeutics as a basis for interpreting and evaluating patient responses to drug therapy.

3. A rigorous exposition of the advantages and consequences of selecting and utilizing drugs in the therapy of disease.

4. A thorough understanding of dosage regimens and those principles influencing dosage regimens such as drug absorption, distribution, metabolism, and excretion.

5. An understanding of (a) the pharmaceutical principles and technology involved in the design, evaluation, dispensing and administration of dosage forms and (b) the various physicochemical factors which influence drug safety and effectiveness.

6. A knowledge of the pathophysiology and clinical biochemistry of disease states and processes as well as an understanding of the significance of the clinical laboratory tests used to monitor disease states and the response to drug therapy.

7. An understanding of the clinical assessment procedures used in the evaluation and interpretation of disease states and processes as a basis for interpreting the selection of and response to drug therapy.

8. An awareness of the sociological and psychological aspects of disease and health care.

9. A knowledge of the techniques used in the interpretation and evaluation of the clinical literature as well as experimental studies in drug therapy and drug product evaluation.

10. An awareness of the methods and organizational structure of delivering health care.

11. Utilization of the Scientific Method in clinical research by developing the ability to identify, investigate, evaluate, and resolve problems in drug therapy and health care.

12. Lastly, in order to integrate, reinforce, and enhance the comprehension and application of the principles and techniques cited above, a rigorous interprofessional clinical experience as provided in appropriate health care facilities.

Pharm.D. Program[a]
College of Pharmacy and Allied Health Professions
Wayne State University

Course Title	Instruction Source	Quarter Credit Hours	Contact Hours
Therapeutic Aspects of Disease - I	CPAHP[b]	3	30
Therapeutic Aspects of Disease - II	CPAHP	3	30
Therapeutic Aspects of Disease - III	CPAHP	3	30
Advanced Clinical Pharmacy Clerkship	CPAHP	12	900
Pharmacokinetics in Drug Therapy	CPAHP[c]	3	30
Pharmaceutical Services in Health Care Facilities - I	CPAHP	3	30
Pharmaceutical Services in Health Care Facilities - II	CPAHP	3	30
Biostatistics	SM[d]	3	30
Social Policies and Health Care	SM	3	30
Clinical Pathology	SM[c]	3	30
Principles of Patient Assessment	SM	1	50
Electives	University	3	30-60
Professional Doctoral Seminar	CPAHP	2	40
Professional Doctoral Project	CPAHP	3	e
		48 (minimum)	

[a] Baccalaureate in pharmacy required for admission

[b] College of Pharmacy and Allied Health Professions

[c] Prerequisite in the baccalaureate program required

[d] School of Medicine

[e] Until completion

WORKSHOP TOPIC 4 - BASIC SCIENCES AND PRE-CLINICAL CURRICULUM
POSITION STATEMENT

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The fundamental purposes of basic sciences in the education of a professional practitioner are four in number.

1. Furnish a rational basis for technical and professional decisions.

2. Provide flexibility for vocational adaptability.

3. Protect practitioner and client from naive acceptance of empirically generated dogma.

4. Mutually reinforcing disciplines promote development, acquisition, and comprehension of basic principles.

The basic sciences represent a rational basis for judgements made in the interest of a client, and thus they represent the technical prerequisites for one to assume responsibility for a party incapable of personal assessment of alternative courses of action or the execution of an appropriate action.

The basic sciences equip the practitioner with technical information and scientific methodology sufficiently broad and yet functionally specific so that he can perform contemporary services and possess at the same time the technical and intellectual capacities to adapt to changing functions which society inevitably will call upon him to perform. This can be extrapolated to include a third function - a strong background in the basic sciences protects the practitioner and his clients from falling prey to empiricism, cultism, husksterism and quackery.

Finally, the basic sciences are mutually supportive. Knowledge in one area permits comprehension of other disciplines, reinforces understanding of interdependent principles, and establishes a unifying concept of natural phenomena.

Because his exact functions in health care are yet to be fully developed, defined, and interprofessionally endorsed, the Pharm.D. graduate requires more basic science preparation for the purpose of adaptability than does the medical or dental graduate. Moreover, there exists a requirement for him to be able to utilize not only the biomedical sciences but also the pharmaceutical science in patient care. Thus there can be no less an emphasis on the physical sciences than on the biological sciences. The sense of the term, "emphasis," as used here is related not to allocation of curriculum time necessarily but rather to mastery of relevant principles. Because contemporary practice requires the baccalaureate pharmacist to apply physical and chemical principles to the preparation and dispensing of compounded medicinal agents and vehicles, an appropriate requirement for competent handling of such principles already exists in baccalaureate education and no further requirements for Pharm.D. education are required in this area.

Other "preclinical sciences,"[1] when taught at a level deemed satisfactory for baccalaureate education, are generally adequate as a basic foundation for doctoral level education and training. Exceptions most commonly noted are anatomy and physiology, especially when these are "...obtained in community colleges and colleges of liberal arts."[1] Such courses regularly fall short of expectations when they are expected to serve as adequate prerequisites for a medical curriculum level of pathophysiology. The test of adequacy is the Pharm.D. students' performance in pathophysiology, and evidence that the performance is substandard in comparison with that of medical students dictates curriculum improvements to minimize this deficiency. It is expected that records will be maintained to demonstrate (1) comparable performances of medical and Pharm.D. students in the pathophysiology courses and (2) appropriate academic and administrative remedial action where such is warranted. These records shall be made available to the accreditation examiners.

In general it can be concluded that, with one notable exception, satisfactory courses in the "pharmaceutical sciences"[2] provided in baccalaureate curricula of accredited programs will be adequate for Pharm.D. curricula. An advanced course in pharmacokinetics should be required to insure that the Pharm.D. student is able not only to comprehend this discipline but he also is adept at solving those types of contrived problems in which modification of dosing and dosing intervals has been shown to have practical importance in patient care. This activity should be further extended into the clinical training in a structured manner so as to optimize the student's clinical use of pharmaceutical sciences and to advance the state of the art. (Time commitment: 30 clock hours)

In comparison with baccalaureate education the differentiating distinction of doctoral level sciences is the intensity of that component identified as the "Biomedical Sciences."[3] An acceptable curriculum would include the following as a minimum core of biomedical sciences.

A. PATHOLOGY - An introduction to fundamental concepts such as may be given in a good baccalaureate course in human pathology will suffice. Histopathology nomenclature adequate to insure the students' ability to read with understanding clinical journals and pathology consults as well as to communicate with clinical colleagues would be expected. (Time commitment: 60 clock hours)

B. PATHOPHYSIOLOGY - A rigorous course in medical pathophysiology is a critically essential component of the Pharm.D. curriculum. In those programs in which pharmacy faculty provide the lectures or such other

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[1] see item 4, b, under "Curriculum and Degrees," page 14, Accreditation Manual 7th ed., The American Council on Pharmaceutical Education, January 1, 1975.

[2] see item 4, c (1), under "Curriculum and Degrees," page 14, Accreditation Manual, 7th ed., The American Council on Pharmaceutical Education, January 1, 1975.

[3] see item 4, c (2), under "Curriculum and Degrees," page 14, Accreditation Manual 7th ed., The American Council on Pharmaceutical Education, January 1, 1975.

media as may be used for instruction, access to academic medical specialists for a minimum of 30% of the course content is considered an acceptable standard. Where the course is not taken with medical students, or where Pharm.D. students are excused from certain components required of medical students, or where either testing procedure or grading standards are different from those applied to medical students, explanation and justification will be anticipated by the accreditation examiners. (Time commitment: 300 clock hours)

C. PHYSICAL DIAGNOSIS - As preparation for monitoring those disease parameters indicative of patient response to specific medication, appropriate instruction in physical examination is required; objectives of the course should include representative drugs, the parameters which should be monitored during their use, and the level of proficiency expected in detecting and interpreting fluctuating values. (Time commitment: 40 clock hours)

D. BIOSTATISTICS AND DRUG LITERATURE UTILIZATION - In the absence of adequate indications that the clinical portion of the curriculum insures competence in selecting, interpreting and evaluating clinical drug literature, a formal course should be included in the curriculum. It should include principles of experimental design for clinical drug studies, acquisition and interpretation of data, statistical analysis and the applications of conclusions. (Time commitment: 45 clock hours)

E. PSYCHIATRY - In addition to pathophysiology, an analagous course dealing with the etiology, natural history, sequellae, etc., in the realm of psychiatric, psychophysiological, and related disorders is necessary for the Pharm.D. curriculum. (Time commitment: 40 clock hours)

F. PHARMACOTHERAPEUTICS - Principles of clinical pharmacology, clinical toxicology and clinical pharmacokinetics should be integrated in an intensive study of pharmacotherapeutics. The course may include a minor component of review material, but it should not be designed or implemented as a pharmacology course. The course content should be derived from current literature and its objectives should be stated in such a manner that outcome is clearly intended to be mastery of the rational basis of drug utilization in clinical practice. (Time commitment: 120 clock hours)

Indicators of adequate preparation of the Pharm.D. student in "Preclinical Sciences," "Pharmaceutical Sciences," and "Biomedical Sciences."[4]

1. The student performs creditably in pathophysiology courses with medical students.

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[4]see page 14, under "Curriculum and Degrees," Accreditation Manual, 7th ed., The American Council on Pharmaceutical Education, January 1, 1975.

2. The student communicates effectively with clinical faculty, medical students and house staff on matters relating to pathological characterizations of patient status. He can understand and summarize for a third party the pathological basis for a diagnostic or therapeutic decision.

3. He can convert available patient data (clinical and laboratory) to an appropriate dosage plan for those drugs requiring pharmacokinetic management.

4. He can locate, evaluate, summarize and communicate clinical literature support for his counselling of students and housestaff on matters of a pharmacotherapeutic, toxicologic or pharmacokinetic nature.

5. Medical students regularly seek his assistance on questions relating to drug use in particular patients.

6. Housestaff share concerns about drug management plans with him, listen courteously to his comments, and frequently follow his recommendations as he gains rapport during clinical training phases of his program.

7. His confidence in the use of pathological, pathophysiological, and therapeutic terms and concepts is apparent from observations of his interactions with other health professions.

8. Clinical faculty are willing to delegate to him at appropriate points in his clinical training increasingly complex responsibilities in service, teaching, and consultation.

9. On a pharmacotherapeutics examination administered to Pharm.D. students within 30 days of their graduation and to a similar number of medical students at the same period in their curriculum, the average performance of the Pharm.D. students will be better than the average achieved by the medical students. Actual patient situations will serve as the source of examination material.

WORKSHOP TOPIC 5 - CLINICAL CURRICULUM
POSITION STATEMENT

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Section 4 of the Tentative Guidelines does not sufficiently define the scope and content of the clinical experience component of the curriculum. The clinical experience component of the curriculum is intended to:

1. Allow the students to develop confidence in their ability to function in a clinical environment.

2. Allow the students to communicate and establish rapport with physicians, other health care professionals and patients.

3. Expose the students to a role model for professional practice.

4. Allow the students to apply their previous education to specific clinical situations.

5. Give the students a basis for further development of clinical competence.

In order to establish a degree of consistency in what kinds of experiences are acceptable as a component of the clinical pharmacy curriculum, it is necessary to define the characteristics of acceptable clinical experience courses. The following characteristics should be present in all clinical experience courses:

1. The experience should include direct patient contact. The student should have interactions with the patient which include assessment of health status (e.g., drug histories) and the provision of patient education.

2. Access to complete patient information. The student should have access to complete medical records including results of laboratory tests, physical examination, diagnosis, progress notes, vital signs and medication orders.

3. A viable, functioning clinical pharmacy role model should be present in the patient care area where students are receiving these clerkship experiences.

4. Preceptorship. The student should have regularly scheduled conferences with a clinical pharmacist throughout his or her clerkship. The preceptor's interaction with the student should include:

   a. Review of student recommendations and presentations prior to their implementation.

   b. Teaching: Preceptor must function as a teacher who can review

with the student the important points of a particular problem and direct the student in self-study.

c. Evaluation: Preceptor is responsible for the ultimate and day-to-day evaluation of student performance. There should be an ongoing effort throughout the clerkship to help students improve in weak areas.

5. Opportunity for professional interaction with other health professionals in the clinical area. The student is expected to interact in the form of consultations, participation in rounds and conferences, in-service education and other activities related to patient care and teaching.

6. The length and intensity of the clinical experience should be sufficient for the students to participate in a continuum of patient care. This will vary depending on the nature of the service, but should be long enough for the students to establish rapport with other health professionals and to provide continuity of care.

7. The student should be thoroughly familiar with an appropriate number of patients. The number will depend on the nature of the clinical area.

8. Since health care is a full-time involvement, the curriculum should be devoid of major didactic courses during the time clinical experience courses are offered.

9. Certain drug distribution activities (including dispensing, supervision of technicians, preparation of intravenous fluids and other technical functions) are more appropriately covered in other courses in the curriculum (including externships) and are not considered to be part of clinical experience courses.

10. A prerequisite to a clinical experience is that the students be properly prepared to function in the environment. A strong basic science background followed by pathophysiology, therapeutics, literature retrieval and evaluation, behavioral science as it relates to health and illness and an understanding of health care systems and issues is required. The academic level of the biological and applied science courses should be comparable to those offered in medical schools.

The following is offered as an example of an appropriate number of hours for these courses in the curriculum:

	Lecture	Lab/Conference
Human Anatomy--Gross	30	60
Histology	30	60
Neurology	30	
Biochemistry	110	
Physiology	100	40
Microbiology	40	60
Pathology	30	30
Pharmacology--General and Toxicology	120	60
Biopharmaceutics--Pharmacokinetics	80	30
Literature Retrieval and Evaluation	30	30
Behavioral Science (Health and Communication)	50	20
Health Care Systems	20	20
Didactic Therapeutics	150	60

11. Externships qualify as clinical experience courses only if they meet the above criteria.

12. All students are required to satisfactorily complete clinical experience courses in the inpatient and outpatient setting.

Clinical Experience Courses:

Inpatient Required - 400 hours minimum

Various services where students are exposed to a reasonable spectrum of general medical problems. This is not necessarily restricted to a general medical service. These 400 hours are an appropriate combination of activities such as rounds, conferences, patient contact, consultation and chart review. Activities directly related to drug distribution are not considered part of the 400 hours.

Outpatient Required - 300 hours

An exposure to an ambulatory environment which meets the criteria defined above. The student should be exposed to a reasonable spectrum of medical problems. These 300 hours are an appropriate combination of patient contact, consultation, conferences and chart review. Activities directly related to drug distribution system (i.e.,

dispensing) are not considered part of the 300 hours.

Clinical Experience Electives

A sufficient number and variety of clinical experience electives should be available so that all students may take a full academic year of required and elective clinical courses. These courses must meet the criteria outlined above. However, clerkships which require more independent study should be available to students who have completed the required inpatient or outpatient experience courses.

WORKSHOP TOPIC 5 - SPECIFIC TYPES OF CLINICAL EXPERIENCES WHICH SHOULD BE PROVIDED BY ALL PROGRAMS

POSITION STATEMENT

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I. In-patient Clinical Experience - Although patients probably spend less than 5% of their ill life in an institutional setting, hospitals and other in-patient institutions maximize clinical experiences because the severity of illnesses seen permit frequent observations of multiple drug use. Moreover, greater concentration of health resources such as personnel, equipment and educational materials are available. Thus, the majority of the total clinical experience (about 60-65%) should be spent in such areas.

Patient contact in conjunction with physicians and nurses is essential to this clinical experience. The student must have the opportunity to develop a bedside manner and patient communication skills (e.g., through drug use interviews). Likewise, the student must have insights into the therapeutic decision thought processes of physicians and must also monitor the daily progress of patients by daily "rounding." As part of this rounding process, the students should know the disease state, its therapy and prognosis; the scheduled plan of treatment which should include therapeutic maneuvers other than drugs; the pharmacology and pharmacokinetics of each drug of each of the patients seen on rounds. The Pharm.D. candidate should not only have these experiences but must also have the responsibility of forming the therapeutic decisions (as opposed to merely having insights) with his health care team. This great responsibility assumes, therefore, a greater quantity of active involvement in the rounding process thereby evolving the Pharm.D. candidate into a more professionally mature graduate. Since this process directly affects patients' health, it should be closely supervised by a clinical pharmacist preceptor for both the baccalaureate and doctoral student. However, the Pharm.D. candidate should have a major portion of his/her clinical activities only indirectly supervised, provided that the clinical pharmacist preceptor is reasonably confident of his/her clinical competence. This partially independent activity allows the doctoral student to assume the consultative responsibilities for the optimal medication care of his/her own patients; and as a result, the student matures more quickly with this increased responsibility.

Clinical rotations through pediatrics, emergency medicine, acute care and general medicine should be required for the Pharm.D. student. Other rotations should be adapted to individual student interests and may include nephrology, hematology, cardiology, rheumatology, etc. Any one such extensive rotation should be adequate for the baccalaureate student who merely needs a laboratory to apply what has been learned from previous courses in the College of Pharmacy. Whatever the rotation, "attending" physician conferences are important for both types of pharmacy students, but the Pharm.D. student should be a more active participant than the baccalaureate student. Active participation implies case presentations and discussions of specific aspects of drug therapy.

During this entire in-patient experience, nursing interactions are essential. The Pharm.D. student would differ from the baccalaureate student only in the degree of nursing involvement (e.g., 700 hours vs. 200 hours). Both should learn from nursing, basic patient assessments (e.g., the importance of apical versus radial pulses, what to observe in patients receiving intravenous therapy), as well as interpersonal patient relationship techniques (e.g., death and dying). The pharmacy students can in turn serve as a bedside pharmacologist to both nurses and nursing students.

The Pharm.D. student should also have a very limited but a direct interface with other members of the health team such as dieticians, respiratory therapists, clinical laboratory personnel, etc. if s(he) has not had such interactions as a baccalaureate student. This activity need not be more than an exposure but it should provide the students an understanding of the various clinical activities, interactions, and terminologies of other health personnel. It also improves the pharmacist's skills in communicating with them. An ancillary benefit of this interaction is the introduction of these other health professionals to the concept of a patient-oriented pharmacist, while simultaneously opening up channels of communications to these health resource persons.

II. Ambulatory Clinical Practice - A well-balanced pharmacist should have an ambulatory care clinical rotation as the majority of ill patients are not hospitalized but rather visit an out-patient facility. Here, one sees the common day-to-day diseases not commonly seen in hospitals. Family practice clinic, pediatric clinic, comprehensive clinic, behavioral sciences clinic, home care clinic, physician office visits, or any other similar rotations should suffice in providing the Pharm.D. candidate with perspectives on rational ambulatory drug therapy. These ambulatory rotations should account for approximately 20% of the clinical curriculum for the Pharm.D. student. In these facilities, the doctoral student should provide patient education as to proper medication usage to insure patient compliance and to minimize potentially disabling side effects. Consultations with physicians in the selection of therapeutic agents, in-service pharmacology conferences to nursing and medical house staffs, and follow-up of patients to insure continuity of care, are important functions for that doctoral student in these facilities. Should adequate facilities and curriculum time be available, the baccalaureate student should also have these ambulatory rotations provided that all activities are supervised. Supervision for the doctoral student, like in the in-patient setting, is dependent upon the clinical competence of the individual.

If these types of ambulatory clinics are either unavailable, or inadequate to meet the needs of the doctoral student, professional community pharmacies may be viable alternatives if the doctoral student has not already availed himself/herself of this training during the baccalaureate years. The professional activities in this environment should entail monitoring of patient medication profiles, patient consultations, working in those areas which benefit community health, and learning efficient drug distribution.

III. Areas of Need

A. Skilled Nursing Facilities - Good medical services have clearly prolonged the quantity of life but social services have been somewhat lacking in improving the quality of life. Since the geriatric population will continue to grow larger as a result of even better medical breakthroughs and as a result of the post-war population boom reaching geriatric status, the pharmaceutical requirements of these individuals will also continue to grow. Pharmaceutical services to these extended care facilities are often provided by pharmacists who have never received any formal training pertaining to these facilities resulting in a quality of pharmaceutical care that too often is woefully lacking. The Pharm.D. student should, therefore, address himself to this need by monitoring the medication therapy of these individuals, by consulting with the visiting physicians, by communicating to patients, by in-servicing the nursing staff, and by closely working with the pharmacist consultant contracted by that facility. It is difficult to gauge the total amount of time needed for this clinical experience; however, it should be minimal (perhaps 5% of the total clinical curriculum). At the very least, both baccalaureate and doctoral students should be exposed to these facilities and their present system of pharmaceutical services.

B. Rural or Inner City Environments - Many rural and inner city communities have difficulty with enticing younger pharmacists to replace those retiring from practice. Due to the maldistribution problem of health care personnel, good in-roads can be made for the provision of patient-oriented pharmaceutical services in these areas. Depending on the community needs and facilities a program should be structured that could substitute for either the nursing home or even perhaps the ambulatory clinic requirement.

IV. Clinical Project - A clinically-oriented project should be a requirement for the doctoral student. This project need not be highly sophisticated but it should at least introduce the student to concepts of controls, random sampling, statistical analysis and evaluations.

V. Supportive Courses - The following supportive courses should be required within the Pharm.D. curricula if not already a part of a baccalaureate program:

A. A minimum of 12 quarter units of applied therapeutics
B. Drug information evaluation for 2 quarter units
C. Intravenous solutions and therapy for 2 quarter units
D. Pharmacokinetics for 6 quarter units
E. Biostatistics for 6 quarter units
F. Basic pathology for 4 quarter units
G. Non-prescription drugs for 3 quarter units
H. Clinical toxicology and adverse drug reactions for 4 quarter units

Sufficient background in arts, humanities and social sciences to produce well educated university graduates, as well as, the traditional pharmaceutical sciences should have been covered in the baccalaureate program.

VI. Elective Courses

A. Immunology
B. Computer applications
C. Drug distribution systems
D. Behavioral sciences
E. Basics of physical diagnosis

VII. Residencies - Residency programs should be established in specialty areas such as residencies in pediatric clinical pharmacy and drug information retrieval. The traditional general clinical pharmacy residencies will hopefully be replaced with the structured Pharm.D. program.

WORKSHOP TOPIC 5 - THE CLINICAL CURRICULUM
POSITION STATEMENT

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The clinical clerkship is the major experiential emphasis of the doctoral program. Students should not receive compensation for their activities during the clinical clerkship experience portion of the curriculum. Compensation carries the danger of placing excessive emphasis on a service component at the expense of the educational component of the clerkship. Students should be closely monitored on a daily basis by a clinical pharmacy practitioner-educator. This faculty member should supervise three or less students during the clerkship and serve as a role model as well.

The clerkship experience must be located in the environment where the student will have the greatest opportunity to learn, ideally, an organized health care setting where teaching and patient care are the primary goals. The clinical experience should have distinct but integrated phases with objectively identified goals.

The constraints on the length of this document prevent discussion of the specific levels of competence to be demonstrated by the students in each skill identified for the clerkship experience. The skills developed in each phase of the experience as outlined should be consistent with professional doctoral training. Additionally, the depth and degree of training should be such that the framework and foundation for the development of expertise is achieved. Achievement of expertise in a specific area is best accomplished through specialty resident training programs.

Phase I - This experience will be integrated with the basic didactic coursework especially pathophysiology, therapeutics and pharmacokinetics. This clerkship should be part time, 16-24 hours/week. Rotations will be based on an organ system approach and coordinated with the aforementioned didactic coursework. The following specialty areas will be required during this clerkship:

Rotation	Weeks in the Area
Cardiovascular	4
Pulmonary	2
Neurology	4
Renal	4
Endocrine	4
Infectious Disease	4
Gastrointestinal	2
Hematology	2
Psychiatry	2
Cancer	2

The student will participate in patient care with a degree of responsibility commensurate with the level of his/her data base and skills. The following specific skills will be developed by the student during this clerkship:

1. Ability to integrate didactic concepts with clinical experience.

2. Ability to observe and analyze the signs and symptoms of disease.

3. Ability to obtain a patient data base for identifying and solving problems

4. Ability to counsel patients about the appropriate use of medications.

5. Ability to organize and present an assessment of the patient's problems.

Phase II - The student will have a full-time commitment to patient care in general medicine (preferably adult internal medicine). The length of the experience will be 16 to 20 weeks. Initially students will be assigned only to a few patients with the patient load increasing as the clerkship progresses. Students will share the responsibility for the development and monitoring of the drug therapy plan with the medical resident and clinical pharmacist. The following specific skills will be developed by the student during this clerkship:

1. Ability to utilize a comprehensive data base in the following areas: pathophysiology, therapeutics, pharmacokinetics and toxicology.

2. Ability to identify and assess patient problems:

   a. ability to obtain medical history and perform physical examinations

   b. ability to use laboratory and radiological findings.

3. Ability to define therapeutic goal(s) and endpoint(s).

4. Ability to select the most appropriate therapeutic agent(s) and regimen(s) depending on patient and drug variables.

5. Ability to monitor the effects of drug therapy based upon selected indices of effect.

6. Ability to implement appropriate changes in drug therapy based upon patient response.

7. Ability to demonstrate a sense of personal responsibility to patients for their drug therapy.

Phase III - Students will have a full-time 16-20 week commitment to patient care during this experience. The major goal of this clerkship is to further develop the students' skills in an area of specialty interest. Students, with the approval of the clinical pharmacy-educator, will develop the objectives for this clerkship. Students will be placed in the patient environment best suited to accomplish defined objectives, i.e., ambulatory clinic, health maintenance organization, hospital specialty area or other organized health care areas.

The clinical faculty will work closely with the students and monitor development and accomplishment of predetermined objectives.

Conclusion - The acceptance of this approach will develop an organized, integrated clinical experience program for the student. This process will insure the development of a sound, functional data base and utilization skills. This approach also provides the opportunity for students to develop their individual interests and goals.

WORKSHIP TOPIC 6 - EVALUATIVE MECHANISMS FOR DOCTOR OF PHARMACY PROGRAMS
POSITION STATEMENT

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Evaluative mechanisms should be closely allied to guidelines concerning curriculum and basic student competencies. Thus, since the evaluative mechanisms are based in part on the particular educational mechanism or design, this design will be mentioned at the appropriate places during discussions of evaluative mechanisms.

The curriculum for a Doctor of Pharmacy degree program should be based on the desire to achieve certain competencies within the individual towards the goal of becoming a clinically competent practitioner. Therefore, the concept of the competency-based education is important within the Pharm.D. program as regards evaluative mechanisms used to assess this competency. In theory, the use of the competency-based curriculum is built on several assumptions:

1. That nothing is innate, but rather all things are learned.

2. That behaviors exhibited by any individual are thus the result of learning.

3. The correlary of number two above is that all learning may then result at any point in time in the expression of a given behavior or set of behaviors.

4. Finally, that competency can be described as a series of behaviors exhibited by any individual in given situations.

Discussions then of evaluative mechanisms are based on the above principles. The goal of a Doctor of Pharmacy degree program is to so modify the behavior of an individual so that in the terminal portion of the program, the behaviors exhibited by the individual closely approximate those previously designated as "acceptable" or "desirable" for a clinically competent practitioner. Thus, evaluative mechanisms are used to determine the stage of development of the body of behaviors of any one individual as they are modified towards the goal of approximating those behaviors of a clinically competent practitioner. More specifically, the competency-based curriculum requires that certain terminal behaviors be defined. These terminal behaviors are the overall objectives of the curriculum, and any competency-based curriculum is defined in its goals and content by behavioral objectives. Evaluative mechanisms should then be designed to measure progress toward achievement of the basic objectives of the program. It is desirable then to develop an indepth set of objectives for a Doctor of Pharmacy degree program, and present them to the student at the beginning of the curriculum.

Specific competencies, as behaviors, require the basics of facts, skills, and concepts concerning drug therapy problems which may be encountered. Thus, a given behavior is in part psychological and in part based on the acquisition of certain amounts of hard data.

In view of the above noted facts, evaluative mechanisms can be suggested which evaluate the acquisition of certain "hard" knowledge which includes facts, skills, and concepts of therapeutics, pathology, pathophysiology, etc., where these bases are necessary to formulate specific competencies. In addition, any activity or any competency is modified by the psychological make-up of the individual and his interpretation of these basic points as well as utilization of his communicative skills, etc., and may be situation dependent. Evaluative mechanisms should also include evaluations of performance in situations which closely approximate the environment in which the desired competencies would be exercised.

In looking to accredit programs under the competency-based curriculum concept, accreditation should be based on the following points delineated by the American Association of Colleges for Teacher Education (AACTE) Committee on Performance-Based Teacher Education. Paraphrasing their recommendations, a program is performance based if:

1. Competencies (knowledge, skills, behaviors) to be demonstrated by program graduates are derived from explicit conceptions of practitioner roles, stated in measurable terms and made public in advance.

2. Criteria for assessing competencies are congruent with specified competencies, make explicit expected levels of mastery under specified conditions and are made public in advance.

3. Assessment of the student's competence is based on his performance, takes into account evidence of his knowledge relevant to planning for, analyzing, interpreting or evaluating situations or behavior and strives for objectivity.

4. The student's rate of progress through the program is determined by demonstrated competence rather than by time or course completion.

5. The instructional program is intended to facilitate the development and evaluation of the student's achievements of specified competencies.

Methods of Assessment

The methods of assessment in any Doctor of Pharmacy program must reflect adequately all components of the educational process so that the sum total of all methods of assessment and not one assessment technique alone may be integrated to more accurately evaluate the student.

Any measurement device is a prescribed situation, concerning one or more traits, in which the testee (learner) is placed, and the situation so contrived that the testee cannot attempt or complete the task without giving evidence concerning the trait in which the tester is interested. Whether or not the contrived situation (test) does what it is intended to do depends upon several factors, such as: the skills of the test constructor, whether the trait is overt or covert, whether desirable secondary behaviors are a correlate of the primary, measured behavior, the types of behaviors acquired or reinforced during

the preparation to answer the test items and the perception of the task by the testee. As a result of examining the examinee in the contrived situation, some objective or relatively objective evidence should be definable and reportable. Reporting undefined scores, marks or measures leads nowhere. The meaning of scores is derived from their exact definition.

Methods of assessment can be basically of two types: Norm-referenced tests and criterion-referenced evaluations.

1. Norm-referenced tests are basically those of the objective format; the student's basic knowledge utilizing some written assessment form. The classic example in this case is the objective test whereby the student answers a certain number of questions asked in a given format. In general, the student is thus performing on a measurement of factual knowledge. In turn, his performance is referenced in many instances by established norms of performance; i.e., the administration of a test is followed by grading and the relative importance of the student's performance as a measure of factual knowledge is graded depending on the norms established for the test. Objective methods of assessment can be of two types: (1) Those methods utilized solely as a test of factual knowledge in a specific area, and (2) those tests utilized in the broad areas covered by any Pharm.D. curriculum as a means of assessing student performance relatively to identify deficiency areas. The latter "test" could then be used to guide the student into various methods of self-education so that his performance can be improved to the norms of his peer group. In the first instance, the examinations would obviously include those facts, skills, and concepts necessary for practice and in turn, the "grade" on this examination could be utilized as a mechanism of evaluation. In the second instance, the rather broad, comprehensive nature of the examination and its stated goal of deficiency area identification would make this less likely to lend itself towards achievement evaluation and thus a "grade" on this examination need not be as important as the relationship of the grade to other student and/or faculty grades on this examination.

2. Criterion-referenced evaluations are a direct outgrowth of terminal behavioral objectives. They are utilized to monitor behaviors which as previously stated are a synthesis utilizing facts, skills, concepts and specific competencies along with psychological make-up of the individual. In the past, rather subjective mechanisms have been utilized to assess student behaviors and obviously lend themselves to bias on the part of the evaluator. The subjective mechanisms many times end up being popularity contests rather than attempts to evaluate students' competencies. By the utilization of terminal behavior objectives, the criterion-referenced tests can evaluate a students' performance based on a decision of how a student is to act made previously by practitioners in a given area. These evaluations can be done for virtually any situation where that situation approximates a practice situation. These situations may include seminar presentations and discussion groups, verbal examinations, and audits of clinical practice.

In the evaluation situations described above, obviously some different behavioral objectives need be applied to each situation. However, the concept remains that students' behaviors are evaluated in reference to previously agreed on behaviors desirable of a clinically-competent practitioner.

When the method or way of performing (behaving) is important, a process measuring situation is devised and each situation can be thought of as a test item. If the end result is more important than the method, a product measuring situation is required. Products can include treatment schemes, literature evaluations, modifications of patient behaviors, systems applications to common problems, and an infinite number of other real things. In many instances, much can be inferred about a process from observing a product; the two are interrelated. Evaluations using processes and products are commonly more reliable than merely testing at the verbal level, which may or may not indicate competence.

1. Verbal examinations: The verbal examination is a mechanism whereby a student may be asked to evaluate a given case. The examination should be administered by a group of the student's peers, assuming these persons to be competent practitioners. A case, presented to the student, can have certain previously defined behaviors assigned to it and thus as the student exemplifies those behaviors, the evaluators award the student a given number of points based on a previously agreed upon scale.

2. Seminar presentations or group discussions: Students may be evaluated on other behaviors such as teaching competence, demeanor, etc., which are different from those noted above.

3. Audit: The most important assessment of the student's abilities in the clinical environment are those made in actual practice. These are, of course, the most difficult to achieve. They are evaluations conducted in an environment which most closely simulates the environment of actual practice (and in some instances, may be the same). Utilizing the criterion-referenced test principle, certain criteria of behavior are established for a student's performance in a given area of therapeutics and agreed on by the evaluators. When a student performs in the clinical environment such as the acquisition of medication histories, patient counseling, interaction with and recommendations to physicians and other allied health professionals, the student's performance is then audited based on these previously agreed upon standards. Audits should include behaviors deemed necessary by the student as well as some indication of the sequence in which these behaviors need be executed as both result and process are important in the overall evaluation of the student.

In summary, the evaluation mechanisms employed in a Doctor of Pharmacy degree program rely heavily on the educational mechanisms utilized in the program. The most desirable educational mechanism appears to be competency-based curriculum. In turn, assessment of competencies can be done by measurement of basic knowledge which the student possesses concerning facts, skills, and concepts as they relate to the area of therapeutics. These basic tenets of knowledge can be measured utilizing standard objective measurement techniques including the written examination.

More importantly, evaluation of competencies relates to behavior modifications that occur in a student which makes him more closely approximate those behaviors of a clinically competent practitioner. The competencies then are assessments of behavior modification and can include assessments of behavior including verbal examinations, seminars, discussion groups, etc.

WORKSHOP TOPIC 6 - EVALUATION AND STUDENT QUALIFICATION *
POSITION STATEMENT

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Introduction

Accreditation may be defined as the process whereby an agency grants public recognition to a program of study which meets certain established qualifications and educational standards, as determined through initial and periodic evaluation.** The accreditation process indirectly serves as a first step for society to evaluate the quality of a graduate of such a program or in the instance of pharmacy, one mechanism for society to evaluate the individual's ability to practice his profession. As with pharmacy, this accreditation process provides then one guarantee for quality health care.

It has been stated that the Doctor of Pharmacy Degree should be the highest award given in recognition of academic preparation for professional practice.** Any such high recognition of preparation requires an accreditation process to justify such claims and to aid the public in recognizing those individuals who possess the talent to render quality health care. At present, the profession of pharmacy relies on the evaluative mechanism of the respective schools and state boards to measure and guarantee professional abilities. These do not, at present, measure the important parameters of performance in the clinical and professional settings.

It is critically apparent then in these times of public accountability and acceptability, that a national uniform and consistent accreditation program is necessary for the Doctor of Pharmacy program.

Accreditation Program

The accreditation process must contain mechanisms to evaluate the quality of the teaching program, the effectiveness of the teaching methods and student performance. The actual process should measure the knowledge of the student and his ability to apply this knowledge to complete tasks. Thus, combining evaluative measurements using behavioral and non-behavioral techniques will ensure accurate, reliable and informative data. The initial thrust of the accreditation process should evaluate student performance, as an indicator of accredited acceptability of the Doctor of Pharmacy programs of the universities. Eventually, tools will be developed to directly measure the quality of the teaching program and the effectiveness of teaching methods.

Therefore, it becomes necessary to develop a tool to evaluate student performance. To accomplish the development of this mechanism, pharmacists possessing the Doctor of Pharmacy degree should be surveyed to provide the necessary functions and knowledge of their current and anticipated practices demonstrated on the basis of health care needs and by example. All prior

*Sections 5 and 6 of "Tentative Guidelines"

preparation for possessing the necessary knowledge to complete tasks must be documented as well as those factors which affect task completion.

Once this data is collected, it should be forwarded to a Review Committee composed of pharmacy educators, pharmacy practitioners and behavioral scientists. This Committee will categorize this information into three areas: 1) knowledge and preparation; 2) task completion and outcome desired; and, 3) factors which affect task completion. Once categorized as delineated above, the prepared document should be distributed to two larger subcommittees; one composed of pharmacy educators and practitioners; the other composed of health legislators, representatives of third party groups, hospital and university administrators and health care advocates for review, comment and acceptance. This agreement will then initiate the development of tools to be used for this accreditation assessment by the Review Committee. After these tools are developed, they should be sent to universities offering the Doctor of Pharmacy program for testing the tool's usefulness and to establish normalcy standards.

Consequently, it then becomes necessary for all universities offering the Doctor of Pharmacy Program to adopt these standards of knowledge and tasks and agree to the use of the mechanisms developed for evaluation. Acceptance of these standards may necessitate curriculum revision to accomplish the goals of education developed for the Doctor of Pharmacy program. The evaluation tools designed must then be integrated into the Doctor of Pharmacy program. Upon successful completion of these nationally-established standards for the Program, the student will petition for external examination. These external examiners, again using the criteria and mechanisms delineated above, will comprehensively test these petitioners using oral and written examinations and behavioral testing designed to be uniform and consistent. These mechanisms should be tested for validity and normalcy as was the internal evaluation methods of each university. Only after successful attainment of both the internal and external standards of accreditation may the student be conferred the Doctor of Pharmacy Degree.

The external examination measuring student performance will be the initial tool used to evaluate Doctor of Pharmacy programs for accreditation. The curriculum standards that have resulted from the survey discussed earlier will provide another form of assessment of the Doctor of Pharmacy Program. Accreditation, therefore, will be granted on the basis of standards that have been established in the area of curriculum and on the results (successful vs. unsuccessful) of student performance on external examinations.

** Reference: Tentative Guidelines for the Program Leading to the Degree of Doctor of Pharmacy, American Association of Colleges of Pharmacy, 7-75.

APPENDIX IV

WORKSHOP PROCEDURES

WORKSHOP PROCEDURES

INSTRUCTIONS FOR WORKSHOP PARTICIPANTS:

Basic Workshop 1 - 120 minutes

After joining the Basic Workshop on the topic assigned to you, proceed as follows:

1. As a group, designate one or more group members who are willing to record your ideas for criteria on newsprint.

2. List all criteria, making sure that all group members contribute their ideas. Spend a few extra minutes generating ideas, brainstorming. At this time you should only be concerned with generating and listing ideas. Do not evaluate or criticize them.

3. Look over all items on newsprint and combine any which overlap. Reduce items to the smallest number without discarding important content.

4. Designate two group members who are willing to record additional criteria during the two Secondary Workshops. One group member should be present during the first, the other during the second Secondary Workshop.

Secondary Workshops I and II - Two sessions, 60 minutes each

During each of the Secondary Workshops one group member should be present to record items on newsprint. To the extent possible, avoid repetition of items at this point.

Other Secondary Workshops participants are invited to leave and add their ideas to other topics.

During the Secondary Workshop, persons in attendance should be requested to review materials developed during the Basic Workshop Session. Their suggestions for addition and comments should be recorded for later consideration during the Basic Workshop II session.

Basic Workshop II - 120 minutes

1. Reduce items (combining those generated in Basic Workshop I and those added by other conference participants) to the smallest possible number without discarding content. Be sure the final list is recorded on newsprint.

2. Each individual in the group should record all items the group has listed on newsprint. Rank-order the items in terms of the importance they have to you personally. Your most important item should have the rank of 1; your second most important item the rank of 2; etc.

3. Now, try to rank-order the items as a group. First, determine which items you agree on. Then determine which items you disagree on most, and for what reasons. Record this information on newsprint. Proceed to work toward consensus with those items which are easiest to agree on, working toward those which are more and more difficult to agree on. You may wish to change the content of some items in the process of consensus seeking. Before you start on this work, re-read the instructions for group decision-making. A copy is attached.

   Spend the rest of this workshop on achieving as much group consensus as possible. For those items left unresolved, record your reasons for disagreement. Remember the decision-making strategies.

4. Designate two group members who will write the report for the group, using the information recorded on newsprint. These group members should also be willing to present and discuss the report on Tuesday and to record major disagreements from the audience.

STRATEGIES FOR GROUP DECISION-MAKING

1. Avoid arguing for your own rankings. Present your position as lucidly and logically as possible, but listen to the other members' reactions and consider them carefully before you press your point.

2. Do not assume that someone must win and someone must lose when discussion reaches stalemate. Instead, look for the next-most-acceptable alternative for all parties.

3. Do not change your mind simply to avoid conflict and to reach agreement and harmony. When agreement seems to come too quickly and easily, be suspicious. Explore the reasons and be sure everyone accepts the solution for basically similar or complementary reasons. Yield only to positions that have objective and logically sound foundations.

4. Avoid conflict-reducing techniques such as majority vote, averages, coin-flipping, and bargaining. When a dissenting member finally agrees, do not feel that he must be rewarded by having his own way on some later point.

5. Differences of opinion are natural and expected. Seek them out and try to involve everyone in the decision process. Disagreements can help the group's decision because with a wide range of information and opinions there is a greater chance that the group will hit upon more adequate solutions.